

# ARIZONA BIOMEDICAL RESEARCH COMMISSION

## REQUEST FOR COMPETITIVE SEALED PROPOSALS RFP NO. FY09-200

Pursuant to the Arizona Administrative Code (A.A.C.) R2-7-104, the Offerors may designate portions of proposals submitted under this RFP as proprietary. Documents incorporated by reference in this RFP package may be reviewed during normal business hours at:

**Arizona Biomedical Research Commission  
15 South 15<sup>th</sup> Avenue, Suite 103-A  
Phoenix, Arizona 85007**

**ARIZONA PROCUREMENT CODE:** The Arizona Procurement Code (Ariz. Rev. Stat. ' 41-2501 to 41-2673) and the Arizona Procurement Code Rules and Regulations (A.A.C. R2-7-101 to R2-7-1010) are a part of this document as if fully set forth herein.

**STATE PURCHASING OFFICE (SPO) VENDOR NUMBER:** You may obtain a SPO Vendor Number by completing the Vendor Registration Application. Please contact SPO for a Vendor Registration packet:

State Procurement Office  
Arizona Department of Administration  
100 North 15<sup>th</sup> Avenue, Suite 104  
Phoenix, Arizona 85007  
(602) 542-5511

### ***CONTENTS*** TIMETABLE

PROPOSAL INSTRUCTIONS – PART A-Q

SCOPE OF WORK STATEMENT

PRODUCT AND VENDOR INFORMATION AND EVALUATION SHEETS

REQUEST FOR COMPETITIVE SEALED PROPOSALS

BIOGRAPHICAL SKETCH

SAMPLE LETTER OF ASSURANCE

CONFLICT OF INTEREST NOTIFICATION AGREEMENT

BUDGET WORKSHEETS

GENERAL PROVISIONS

## **TIMETABLE**

Advertisements of Legal Notice will run the weeks of ..... November 3, 2008 and November 10, 2008  
Deadline for Receipt of Written and e-mail Requests for Technical Assistance.....November 17, 2008  
Deadline for Submission of Proposals ..... December 1, 2008  
Proposal Opening ..... December 2, 2008  
Proposed Term of Contract Awarded under this RFP ..... on or before January 1, 2009 to December 31, 2011

# PROPOSAL INSTRUCTIONS

## Introduction

The ABRC intends to establish a centralized, web-based biological specimen tracking database system (the ABRC system) and associated software, which will support a single view of the bio specimens (fresh and frozen tissue, paraffin blocks, cell lines, blood, serum, sputum DNA, RNA and etc.), and note the existence of specimen-related data (clinical, genomic, proteomic and etc.), which are stored in repositories at a number of Arizona hospitals and research facilities and available for acquisition and use by researchers at participating institutions. The ABRC system will represent the information about the available specimens in a consistent and virtual manner and allow the researchers to browse and query the specimen universe in order to determine which specimen may be suitable for their needs.

ABRC intends to license and utilize an already existing software system, such as a commercial-off-the-shelf (COTS) product, or software associated with an existing bio specimen repository service, which may be customized, modified and/or enhanced in order to fulfill the minimum functional requirements set out in the Scope of Work. The licensing period will be set to match the term of this contract, which is anticipated to be three (3) years. ABRC will not engage the services of a contractor proposing to develop new or customized code that is not an extension of an existing software product or software service offering. Offerors are required to submit three (3) references of customers already using the base product or service offering as part of their proposal.

Proposals must be submitted in accordance with provisions, specifications, and instructions stated within this Request for Proposals (RFP).

## A. COST OR PRICING DATA

Cost or pricing data is required under this RFP.

## B. TECHNICAL ASSISTANCE

### 1. Written Questions for Technical Assistance

Questions for technical assistance shall be in writing or in the form of an e-mail and shall be submitted to:

Executive Director  
Arizona Biomedical Research Commission  
15 South 15<sup>th</sup> Avenue, Suite 103-A  
Phoenix, Arizona 85007

Or to:

e-mail address: [james.matthews@azabrc.gov](mailto:james.matthews@azabrc.gov)  
Subject line should read "RFP09-200"

### 2. The deadline for receipt of written questions is 3:00 p.m. local time, November 17, 2008.

Commission responses to questions for technical assistance shall be mailed and e-mailed to each RFP recipient within seven (7) working days after the submission deadline.

## C. INTENT TO RESPOND AND AMENDMENTS TO RFP

**Organizations which receive or download copies of the RFP package and intend to submit proposals in response are encouraged to notify ABRC of their intent.** Notices of intent may be written or e-mailed to ABRC, using the addresses give in Section B, above. ABRC will maintain a list of those organizations and

will use this list to distribute amendments to the RFP. Any and all amendments to this RFP shall be sent to all such listed RFP recipients by first class mail or e-mail, and will also be posted on the ABRC web site. It is the responsibility of each offeror to ensure that they have read and complied with all amendments to the RFP. **Copies of all amendments must be signed by an authorized representative of the offeror's organization and returned with the proposal.**

#### **D. SUBMISSION OF PROPOSALS**

One original proposal, seven (7) copies, and an electronic copy (in PDF format) must be **received** (not postmarked), in a **sealed** envelope or box **clearly marked "PROPOSAL RFP No. FY09-200" no later than 3:00 p.m. local time on December 1, 2008** at the Arizona Biomedical Research Commission, 15 South 15<sup>th</sup> Avenue, Suite 103-A, Phoenix, Arizona 85007. No facsimiles or e-mails will be accepted. **Late proposals will not be accepted or considered.**

#### **E. PROPOSAL OPENING**

Proposals shall be opened publicly at the place and time specified below:

Place:

Arizona Biomedical Research Commission  
15 South 15<sup>th</sup> Avenue, Suite 103-A  
Phoenix, Arizona 85007

Time and Date:

10:30 a.m., December 2, 2008

#### **F. POST-PROPOSAL SUBMISSION DISCUSSIONS AND REVISIONS**

1. Discussions **may** be conducted with responsive offerors who submit proposals determined to have a reasonable chance of being selected.
2. In conducting discussions, there shall be no disclosure of information derived from competing offerors.
3. Proposal revisions **shall** be permitted after the submission and before award for the purpose of obtaining best and final offers.

#### **G. MULTI-YEAR CONTRACTS**

1. Contracts with the Arizona Biomedical Research Commission may be entered into for a period not to exceed three years, unless deemed in the best interest of the State. Awards of more than one year are contingent upon the availability of funds, demonstration of sufficient progress toward Contract goals and timely submission of required reports.
2. If monies are not appropriated or otherwise made available to support continuation of performance in a subsequent fiscal period, the Contract shall be cancelled and the Contractor may only be reimbursed for the reasonable value of any nonrecurring costs incurred but not amortized in the price of the materials or services delivered under the Contract or which are otherwise not recoverable. The cost of cancellation may be paid from any funds available for such purposes.

#### **H. EVALUATION FACTORS and CRITERIA**

The following factors and criteria shall be used to evaluate proposals submitted in response to this RFP. Where the same term is used to describe the relative importance of more than one evaluation factor, those evaluation factors are deemed of equal importance.

**Evaluation Factors:****Relative  
Importance**

- |  |          |
|--|----------|
| 1. Ability of the offeror to deliver a software solution that fulfills all of the stated functional requirements for the proposed ABRC bio specimen tracking system, as demonstrated by proposed approach to the work, and responses to vendor evaluation sheet questions.   | Maximum  |
| 2. Demonstrated existence of a basic software offering or service that the vendor has previously licensed to government or commercial clients that performs a majority of the functions being called for in this RFP for the ABRC bio specimen tracking system.  | Maximum  |
| 3. Experience and expertise of personnel being proposed for the work, specifically the Project Manager and key technical staff. Demonstration of the ability of these personnel to: implement the proposed enhancements to the offeror's existing software; and, provide adequate training, documentation, user support and on-going operations for the ABRC bio specimen tracking system. | Maximum  |
| 4. Appropriateness of the budget request. The proposed budget will be evaluated to assure that it is reasonable relative to the proposed project plan and work effort for both the development and implementation of the ABRC bio specimen tracking system, and its on-going operations.   | Moderate |
| 5. Possession by the offeror of relevant certification(s) in industry standard software development and project methodology practices and principles, and the current application of those practices and principles.   | Moderate |

## I. REVIEW PROCESS – ALL PROPOSALS

### 1. *First level of review:* **STAFF REVIEW**

All proposals are reviewed for compliance and responsiveness with Request for Proposals. **Proposals shall be eliminated from further review if determined to be materially incomplete according to the instructions set forth in the RFP.**

### 2. *Second level of review:* **PEER REVIEW (EXTERNAL)**

Technical evaluations are obtained from out-of-state peer reviewers. Peer reviewers are information technology, health and medical experts recruited in accordance with the elements of the scope of work that have been established by the Commission for this RFP and the ABRC bio specimen tracking system. The Commission will utilize a panel of at least three outside peer reviewers for responses to this RFP.

### 3. *Third level of review:* **COMMISSION REVIEW**

The Commissioners will review the proposals submitted in response to the RFP in their entirety, the lay summaries, and the peer reviews. **The ABRC has three lay members. Offerors must describe the proposed project in clear, concise, non-technical language in the abstract and lay summary. In the executive summary, technical terms should be used only as necessary, and all acronyms should be defined at the point of their first use in the discussion.** The lay summary and executive summary must state the offeror's plan for the implementation and operation of the ABRC bio specimen tracking system clearly. What the offeror plans to accomplish must be made clear and understandable to the lay reader. Information in the abstract will be published and provided to members of the public requesting information. If a proposal has not been reviewed or has only been partially reviewed by the panel of peer reviewers, the Commission may, nevertheless, review and consider the proposal.

## J. CANCELLATION

The Commission reserves the right to cancel this solicitation and any or all proposals may be accepted, modified or rejected in whole or in part. Offerors are advised not to automatically expect three years of support if selected for funding even though three years of project budgeting is a requirement for proposal submission. Awards may be made for a shorter period.

## K. NOTIFICATION OF CONTRACT AWARD

1. Each offeror shall be notified in writing of the Commission's decision to select or reject the proposal for a contract award.
2. Unless otherwise notified, the offeror that receives a contract may consider their proposal approved for the duration of the three year award. **All Contract awards are made subject to the availability of funds. Additionally, continuation of Contracts is subject to demonstration of sufficient progress toward Contract goals and timely submission of required reports.**

## L. COMPONENTS OF COMPLETE PROPOSAL AND CHECKLIST

The completed proposal in response to this RFP shall consist of the following components **in the order listed:**

1. **Request for Competitive Sealed Proposals** form, completed, with all sections filled out, except where noted. The form is included in the RFP packet.
2. **Abstract and Lay Summary** – The Abstract is restricted to a maximum of 150 words. The Lay

Summary is restricted to one page. The form for these items is included in section Q, below.

3. **Executive Summary** – The Executive Summary is restricted to a maximum of 20 pages and provides a description of the offeror’s base product or service and how that software will be used to satisfy the Scope of Work requirements. Further instructions are found in section Q, below.

4. **Completed Product and Vendor Information and Evaluation Worksheets** – Instructions on how to complete the Product and Vendor Information and Evaluation sheet forms will be found in section Q, below. The Worksheets themselves are included as attachments to the RFP package. Offerors must provide responses to all items contained in these forms.

5. **Completed Budget Worksheets** – Instructions for the cost and pricing information that must be supplied as part of the proposal are set out in section Q, below. Budget Worksheet forms, which are to be used to provide this cost and pricing information, are included as attachments in the RFP packet.

6. **Biosketches** – For Project Manager and key technical personnel being proposed for the contract. Use the Biosketch form contained in the attachments to the RFP.

7. **Letter of Assurance** – A sample is included in the RFP packet.

8. **Conflict of Interest Notification Agreement** – The language to be used is included in the RFP packet.

9. **General Provisions**- Review the General Provisions and retain a copy for your records. *A copy of the General Provisions, which are provided in the RFP packet, must be attached to the original proposal only.*

**One original proposal and seven (7) hard copies, plus an electronic copy (in PDF format)** shall be submitted. The hard copies of the proposal shall be clipped together with binder clips. Do not submit bound or stapled proposals. Identify the proposal with original signatures, “ORIGINAL” in section 2 of the Request for Competitive Sealed Proposals form and place it on top. If your proposal contains original photographs or other materials that are necessary for the peer reviewers, you may mark section 2 of the Request for Competitive Sealed Proposals form for 4 of the 7 copies as “PEER REVIEWER COPY”. These 4 copies shall be placed directly beneath the ORIGINAL.

## **M. CERTIFICATE OF INSURANCE**

Insurance shall conform to the General Provisions of the contract. The State of Arizona Certificate of Insurance, RM-7200.1(4/89) shall be completed by offeror’s insurance company/authorized representative and shall be submitted to the Commission with the successful Offeror’s signed contract. The Contractor shall be responsible for providing an updated Certificate of Insurance should any policy terminate during the term of the contract. Arizona’s three public universities and state agencies are not required to submit a Certificate of Insurance.

## **N. SPECIAL REQUIREMENTS**

1. In accordance with A.R.S. §35-397, Offeror hereby certifies that the Offeror does not have securitized business operations in Iran and Sudan.

2. In accordance with A.R.S. §41-4401 the Offeror warrants compliance with the Federal Immigration and Nationality Act (FINA ) and all other Federal immigration laws and regulations related to the immigration status of its employees.

## **O. COST OF PROPOSAL PREPARATION**

The state shall not reimburse the cost of developing, presenting, or providing any response to this solicitation.

## **P. NOTICES, CORRESPONDENCE AND REPORTS:**

### **1. Payment and Billing Method:**

Payments shall be made within 45 days of receipt of complete and accurate progress and expenditure reports

from the Contractor.

**2. Program Reporting Requirements:**

- a. *Expenditure Reports*  
The Contractor shall submit to the Commission Quarterly Expenditure Reports. The first three reports must be filed within twenty (20) days of the end of each quarter. The Annual Expenditure Report must be filed within sixty (60) days of the end of the fourth quarter.
- b. *Progress Reports*  
The Contractor shall submit Monthly Progress Reports to the Commission. The Monthly Progress Reports are due ten (10) days after the end of each month. An Annual Progress Report must be filed within sixty (60) days of the end of each contract year.
- c. *Other Reports*  
The Contractor shall submit such other reports as may be required by the Commission for the purpose of determining contract performance. Supplementary materials may be requested at the Commission's discretion at any time during the contract period.
- d. *Notices, Correspondence, Reports, and Payments from the Contractor* shall be sent to:

Executive Director  
Arizona Biomedical Research Commission  
15 South 15<sup>th</sup> Avenue, Suite 103-A  
Phoenix, Arizona 85007  
Phone: (602) 542-1028

**Q. PROPOSAL SECTION FORMS AND INSTRUCTIONS**

This section consists of instructions for completing five (5) required sections of the proposal:

- Abstract and Lay Summary
- Executive Summary Response to Scope of Work Statement
- Product and Vendor Information and Evaluation Worksheets
- Budget Worksheets (Cost and Pricing information)
- Biosketches for Project Manager and Key Technical Staff



## **1. ABSTRACT AND LAY SUMMARY**

**Company:**

**Name of Project Manager:**

The Abstract and Lay Summary section of the proposal response is in two (2) parts, an Abstract and the Lay Summary itself. The Abstract is different from the Lay Summary. Do not exceed 150 words in the Abstract. The abstract is meant to serve as an extremely succinct and accurate description of the proposed work when separated from the application. If the proposal is funded, the abstract, as is, will become public information. Therefore, do not include proprietary/confidential information in the Abstract. The lay summary is a concise and accurate (one page maximum) summary of your proposal in non-technical, lay language, describing the offeror's base product or service offering, and its approach to satisfying the Scope of Work and delivering a bio specimen tracking system that fulfills all of the requirements set out therein. The Lay Summary will be part of the review package received by all Commissioners, along with the Peer Reviewer analyses.

**Abstract (maximum 150 words):**

**Lay Summary (maximum one page, 10 point type or larger):**

## **2. EXECUTIVE SUMMARY RESPONSE TO SCOPE OF WORK STATEMENT**

The offeror selected by ABRC to be the contractor shall provide all necessary resources to implement, operate and maintain the ABRC bio specimen tracking system in accordance with the tasks and functional requirements as provided in the Scope of Work document, and including the requirement that all identified *milestones*, noted in that document, shall be met. Therefore, in this Executive Summary, the offeror shall provide a description of its base products or services and how they will be used to satisfy the Scope of Work's task and functional requirements, and how the offeror intends to meet all specified milestones. Specifically, the offeror should describe its plan for enhancing or extending the base software product, and the anticipated work effort needed, to meet ABRC's functional requirements. Include a project timeline for the effort that shows when milestones will be completed. The full text of the Scope of Work can be found in the attachments to this RFP document. **The Executive Summary response is restricted to a maximum of 20 pages.**

## **3. PRODUCT AND VENDOR INFORMATION AND EVALUATION WORKSHEETS**

In this section of its proposal, the offeror shall provide a responses to the questions set out in the Product and Vendor Information and Evaluation Worksheets to be found in the attachments to this RFP package. These items will be used to evaluate the offeror's capability to satisfy ABRC's minimum requirements in the areas of: Software product requirements; Hardware and Software Product Information; Service and Support; and, Vendor Profile. Responses must be provided for all questions/items set out in the worksheets. Use the worksheets themselves, or facsimiles which utilize the same information areas and formatting, to provide the indicated responses.

## **4. BUDGET WORKSHEETS – COST AND PRICING INFORMATION**

In this section, the offeror shall provide cost and pricing information for the proposed ABRC bio specimen tracking system solution. The offeror shall utilize the budget worksheets provided as an Attachment to the RFP package. Specifically, the offeror shall supply a price quote for the following cost elements of its proposal:

1. Base system price with a detailed breakdown of the product components required to provide the solution you are proposing for the following:
  - a. Server, assuming that contractor will host the ABRC bio specimen tracking system, or assuming use of a third party to host the server. Please note which alternative is being used in the proposal.
  - b. Basic software product license and fees (note term of license should cover the three year contract period, less the time required to enhance the basic product prior to implementation of the ABRC bio specimen tracking system solution)
  - c. Additional software modules needed to meet all stated functional requirements for the ABRC bio specimen tracking system, and their license cost and fees (describe each module's specific purpose as they relate to the functional requirements).
2. Proposed cost for enhancement/extension of the basic software product to fulfill specific ABRC system requirements, plus estimated hours of effort to effect these enhancements. Using the budget worksheets, provide quote details for required tasks and all required functional areas for the ABRC bio specimen tracking system, as set out in sections D and E of the Scope of Work.
3. Implementation and installation costs to initiate the system, including data migration and role-based user account initiation.
4. Maintenance license and fee costs. Note options, if any, and duration with an expectation of a three (3) year contract term. Note whether standard maintenance costs include vendor's upgrade and patch releases.
5. On-going costs for the operation and maintenance of the ABRC bio specimen tracking system, to include product support, server operations, database management, account management, scheduled backup and maintenance of software and hardware, and any other costs that will be charged to ABRC (specify the nature of and reason for all such other costs).
6. Training costs, if not included in standard licensing costs.

7. Manuals, documentation and media costs, if separate from costs quoted above.
8. Support and help desk costs, if separate from costs quoted above.
9. Costs for software upgrade releases and patches, if not included in maintenance costs.
10. Provide a quote for additional consulting or software development, should any be requested, and the basis on which such costs would be calculated, such as rates by skill category per hour or per day.

## **5. BIOSKETCHES**

The offeror shall provide a biosketch (short resume) for the proposed Project Manager and for each key member of the technical staff who is expected to contribute significantly to the effort to design and implement the ABRC bio specimen tracking system solution. The purpose of these biosketches is to provide ABRC reviewers and Commissioners with demonstrable evidence of the experience and skills possessed by the offeror's software development and operations team.

Offerors should complete a biosketch form, which is included in the attachments to the RFP for the Project Manager and for each key technical staff member. Each biosketch should be no longer than four (4) pages in length. Please limit the number of biosketches to those staff members who are intended to play a major role in the project effort.

## **Scope of Work**

### **A. Background**

The Arizona Biomedical Research Commission (ABRC) requires a contractor to implement a centralized, web-based, bio specimen tracking database and associated software, referred to here as “the ABRC system”. The ABRC system will support a secure, fully de-identified, single and consistent view of key information about specimens (fresh and frozen tissue, paraffin blocks, slides, cell lines, DNA, RNA, blood, serum, sputum, and etc.) which are owned by and stored at a number of Arizona hospitals and research facilities and are to be made available for acquisition and use by researchers performing qualified studies.

**ABRC intends to license and utilize an already existing software system, such as a commercial-off-the-shelf (COTS) product, or software associated with an existing bio specimen repository service, which may be customized, modified and/or enhanced in order to fulfill the minimum functional requirements set out in section D, below. The licensing period will be set to match the term of this contract, which is anticipated to be three (3) years. ABRC will not engage the services of a contractor proposing to develop new or customized code that is not an extension of an existing software product or software service offering. Offerors are required to submit three (3) references of customers already using the base product or service offering as part of their proposal.**

As of the time of the release of this Request for Proposals (RFP), the identity and number of institutions which will participate with ABRC and agree to allow some or all of their bio specimens to be represented in the ABRC system database is not known. Of those institutions that may choose to participate, some have fully functioning bio specimen repositories and use sophisticated software systems to track and manage their contents. For these institutions, the ABRC system will interact, primarily via data exchanges, with the institution’s existing system. Other institutions have rudimentary bio specimen repositories and/or IT tools and databases, and may wish to adopt the ABRC solution for use with their own repositories. In these cases, depending upon the exact solution implemented by the contractor, and the needs of the institution, the institution can elect to utilize the ABRC system as their primary repository tracking and management solution with no additional licensing required, or they may decide to contract separately to acquire licensing for their own version of the ABRC system.

### **B. Objective**

The objective of this contract is to establish an operational ABRC system that will capture and represent de-identified information about available bio specimens from multiple sources in a consistent and virtual manner and allow registered researchers to browse and query the specimen universe, determine which specimens may be suitable for their needs, and request, possibly after receiving additional information from the source institution, that those specimens to be shipped to them. The ABRC system will generate shipping requests to the source institutions, track shipping of specimens, receipt of specimens, and disposal or return of unused specimens or portions thereof.

### **C. Scope of Service**

The contractor shall provide all necessary resources to implement the ABRC system in accordance with the tasks and requirements as provided below, and including the requirement that all identified *milestones*, noted below, shall be met.

### **D. Tasks**

Independently, upon contract award, the contractor shall:

1. Execute a thorough review and analysis of the requirements set out for the ABRC system in order to refine those requirements and generate a final Project Plan and Budget that will serve as the

binding road map for all work during the project period. This effort will collectively be referred to as the **Discovery Phase** of the overall effort. It will consist of the following sub-tasks:

- i. The contractor will meet with ABRC management to review and discuss ABRC virtual bio specimen repository system requirements as set out in the RFP (this document), and to examine additional materials held by ABRC that will pertain to the needs of the medical community that is expected to participate with ABRC in the supply of specimens and/or research using those specimens. Issues to be discussed will include: identification of potential sources of specimens; approaches to resolving the use of disparate vocabularies by different institutions so that a standardized vocabulary can be selected or developed that will allow for common comparison of specimens from different sources by researchers; requirements for the training of staff at participating institutions in Good Clinical Practice (GCP), Good Laboratory Practice (GLP) and in the use of the ABRC system's software tools, and how the contractor will design and implement training and support services to meet those requirements; and, additional functionality, beyond that described here, that the contractor and ABRC mutually determine should be included in the ABRC system.
- ii. The contractor will meet with potential bio specimen sources in Arizona, including research hospitals which already have specimen banks of varying sizes, to review their current specimen creation, storage, dissemination, tracking and disposal policies and procedures, and to discuss their possible participation as sources for the ABRC system. During these meetings, the contractor will determine, in as much detail as is required at this point in the definition of the ABRC, how the required information about specimens owned by each source institution would be transmitted to the ABRC system's software for processing to create de-identified ABRC bio specimen records. Issues to be addressed include: the state of existing specimen software/database tools at the source and how required specimen information would be extracted and transmitted to the ABRC system; and, the vocabularies currently in use at the source to describe the specimen and whether those vocabularies can currently be mapped to the proposed standardized vocabularies, or if effort will be required to perform that mapping prior to the implementation of the ABRC system.
- iii. The contractor will use the information and knowledge gained during this Discovery Phase to prepare and **submit a project plan (including a timeline/schedule and associated level of effort), a revised set of functional requirements, and a final project budget to ABRC for review and approval within four (4) weeks** of the date of the initial meeting between ABRC and contractor staff after contract award (*milestone 1*). The **project plan**, which should follow the task order set out in the remainder of this section, will provide a detailed outline, to the WBS level, of all proposed work to: organize (from the contractor's base software and including additional modules modified or specifically developed to satisfy ABRC requirements); test and finalize all ABRC software; initiate, test and fully populate the ABRC database (data migration); and, implement, test and launch the fully operational ABRC system. Levels of effort by job category and/or experience level (such as programmer, subject matter expert, etc.) should be included in the project plan. The project plan should clearly show overall timelines for the effort and when milestones will be completed. The timeline should not extend the period of performance beyond that proposed initially, except to incorporate additional requirements for the ABRC software that were not anticipated in the original schedule. The revised **functional requirements** shall incorporate the full set of such requirements set out in section E, below, and any additional functional elements that are requested by ABRC as a result of the work done by the contractor during the Discovery Phase. These may include specific features of the contractor's COTS software or basic software service offering. The revised **budget** shall reflect any significant modifications to the scope of work that have been noted as requirements during the Discovery Phase, but must both be

agreed upon by ABRC and conform to pre-existing funding limits for the ABRC system effort. ABRC shall review the work plan, revised requirements and revised budget and respond with specific requests for changes to the contractor within two (2) weeks of receiving those documents. The contractor shall incorporate all changes requested by ABRC into the documents and submit final forms of each within five (5) days (*milestone 2*). Once finalized, each of these documents shall be considered binding and may not be altered or amended without the written consent of ABRC. The contractor shall then execute the approved work plan, including, at a minimum, the basic tasks set out in the remainder of this section.

2. The contractor shall **modify or enhance** their COTS or basic service offering **software** to give it all of the functionality required by the ABRC software functional requirements set. The contractor shall provide a status report on progress made towards completing all required software modifications and enhancements every month (*milestones 3.1 to 3.n*). The report shall summarize work performed during the previous month, estimate percentage completed for each work plan heading, note any unanticipated problems encountered with the software and how the contractor will mitigate each problem, and reaffirm the delivery schedule agreed upon under the work plan.
3. The contractor shall establish the ABRC **database model** in accordance with the requirements set. The model shall be presented to ABRC and other participants during a meeting (*milestone 4*) in which the contractor shall explain the specimen database model, and how the model and the ABRC software will work together to satisfy all stated requirements. Any questions raised at this meeting will be addressed by the contractor and resolved to ABRC's satisfaction.
4. The contractor shall **define and develop the training materials and on-line help documentation** that shall be delivered and installed as part of the ABRC implementation cycle. A training curriculum and training schedule for all major user roles shall be developed and submitted to ABRC for approval (*milestone 5*). Training may be delivered using any media and methods that have been agreed to by ABRC, such as classroom (with hands-on exercises), webinars, or desk side. On-line help should be implemented in a manner to be context sensitive and to enable the "average" user to resolve the great majority of his or her questions without the need to use manuals or to contact a help desk for support.
5. The contractor shall **develop a test plan** for the ABRC software and database system (*milestone 6*). The test plan shall be designed to exercise all ABRC software modules, invoke all logic paths within those modules, and explicitly determine that the set of ABRC specimen records will be fully and correctly created, maintained, altered, and deactivated by transactions executed by the ABRC software. Specific attention in the test plan shall be paid to: the initializing data migration activity of moving bio specimen record information from each source institution's database(s) to the ABRC database before the ABRC is put into production use; and, the transmission of external specimen record information into the ABRC system for the purpose of creating or updating ABRC database records, and to the accuracy of system responses to user defined queries that result in the display of specimen records meeting query-defined research requirements.
6. The contractor shall **execute the test plan** by initiating a test instance of the ABRC database, populating it with test data, and running the ABRC software against that test data. Any identified deficiencies exposed during the execution of the test plan shall be noted and resolved. The testing shall continue until it can be shown that the software is complete and operating correctly (all portions of the test plan have been executed cleanly within a single execution of the plan), and that the overall integrity of the ABRC database and its contents is preserved continuously and without interruption during all testing scenarios (*milestone 7*). When this testing cycle is completed, and it has been demonstrated that the ABRC system meets all requirements, it will be deemed to be accepted by ABRC, and such acceptance will be noted in writing by ABRC. As a final test, the contractor shall work with ABRC to execute ABRC database backup and restore procedures, which may utilize software that is not a part of the ABRC software implementation,

- to demonstrate that the capability of reinitiating a complete, accurate database after a catastrophic failure or non-fatal corruption is present (*milestone 8*).
7. The contractor shall undertake the **execution of the training curriculum** according to the training schedule for all designated ABRC and participating specimen source trainees (*milestone 9*). Basic training of key users at ABRC and each participating source institution will be completed by the time of the initiation of the production ABRC system. Training will continue after the ABRC system is in production to teach additional source institution staff, and research users, as required.
  8. The contractor shall **put the ABRC system into production**. The contractor shall perform a full data migration of bio specimen information from all participating sources to initiate the ABRC database for production purposes, install the production version of the ABRC software, and work with ABRC to ensure that the database is fully populated with clean, accurate specimen records (*milestone 10*). The contractor shall be available to assist the ABRC with the creation of all classes of user accounts. The contractor shall initiate the agreed upon help desk service on the day that the ABRC system goes into production (*milestone 11*). This help desk service and all other contractor support will be delivered continuously for the remainder of the contract period.
  9. For the period of time remaining in the contract after the implementation of the production ABRC system, the contractor shall provide operations and maintenance services for the server on which the system is hosted, communications lines that allow users to connect to the server and the system, and for the ABRC system software. This shall include database backup and other, standard operational tasks. The contractor will meet or exceed agreed upon levels of system availability and guarantees regarding disaster recovery.
  10. For the period of time remaining in the contract after the release of the production ABRC system, the contractor shall **respond in a timely manner to reports of apparent system bugs, incorrect or missing functionality, or other deficiencies** which potentially may compromise the ABRC system. Timely response will be understood to mean that all reported incidents and issues will undergo initial review by the contractor within 48 hours, unless the problem has disabled the system, in which case the contractor shall initiate work to identify the problem and resolve it within 24 hours.
  11. For the period of time remaining in the contract after the release of the production ABRC system, the contractor shall offer to **provide ABRC with all standard software upgrades** that are delivered to customers of the base software upon which the ABRC system is constructed. ABRC shall have the option of installing any such upgrade under the licensing agreement that is already in place, but may also elect to defer or decline to upgrade at its sole discretion without any loss of support from the contractor.
  12. Should the ABRC wish to **add new functionality** to the ABRC system after its implementation and acceptance, it will negotiate the terms and conditions for such improvements with the contractor in a separate agreement or under a modification to the base contract.

## E. Functionality Requirements

The ABRC system, which will consist of the ABRC database and associated ABRC software, will be required, at a minimum, to support the high level features and functionality described below. The ABRC system must be:

1. Capable of supporting a minimum of 10 secure, concurrent, role-based, active user sessions via web-based (preferably web services based and portal accessible, using digital certificates or SSL to guarantee that system access will be only by authorized users) and direct (LAN/WAN) connectivity. Web-based system services should be operable upon industry-standard platforms, and provide standardized interfaces, using tools such as Apache Tomcat, XML-RPC, etc.
2. Capable of creating, storing, maintaining, modifying and deleting (marking as unavailable) an unlimited (or large, i.e. greater than 500,000) number of de-identified, HIPAA compliant, unique, unambiguous

ABRC bio specimen database records that contain information based upon a minimum set of record elements (database fields). The final list of record elements will be determined in consultation with the contractor as part of the Discovery Phase of the contract effort, which is described above, but, at a minimum, should include:

- a. A unique record identifier that is completely patient de-identified (per HIPAA standards) for viewing by ABRC system users, but which will allow the determination of the institution at which the specimen is physically stored and the internal identifier of the physical specimen at that institution for purposes of generating specimen shipping requests;
  - b. The vocabulary used in the source data from which the ABRC record has been built, unless that vocabulary is implied as the standard for all samples from an institution (ICDx, SNOMED, HL7, LOINC, etc.);
  - c. Sample type or format (tissue, blood, serum, sputum, etc.);
  - d. Processing method (cell culture, cell lines, DNA, fixed, formalin-fixed paraffin-embedded, fresh tissue, frozen tissue, OCT, RNA, slides, snap-frozen in liquid nitrogen, tissue microarray, touch prep slides, etc.);
  - e. Anatomic/organ site (if applicable);
  - f. Morphology (cellular characterization);
  - g. Clinical/pathological diagnosis (using ABRC system standard vocabulary terminology);
  - h. Stage of the disease (if applicable);
  - i. Quality (typically RNA quality for frozen tissue);
  - j. Patient demographics, to include
    - i. Patient's age, in years, at the time the sample (biopsy/autopsy) was taken,
    - ii. Patient's sex,
    - iii. Patient's race or ethnic origin.
  - k. Existence of other data associated with the specimen (listed by type, i.e. clinical, tissue, pathological, gene expression data, proteomic data, characteristics regarding medications taken, treatment, longitudinal data, x-rays, blood tests etc.) that will not be stored with the bio specimen record in the ABRC database. These will be yes/no type fields that will allow a researcher to know that additional information has been captured. A researcher will be able to use the ABRC system to request that information, or a summarized version of it, be supplied to him before deciding whether or not to order the specimen;
3. Capable of mapping vocabulary-based information contained in a source institution's records to a standardized ABRC vocabulary. Each external bio specimen source will have its own set of definitional data record elements and will use one or more specific vocabularies to express medical and diagnostic terms. The ABRC software must be capable of mapping the terms used in the specimen records provided by each external source against a single standard vocabulary to allow for the creation of ABRC database records which will provide unambiguous, uniform terminology application across all specimen records.
  4. Capable of the input of tissue specimen information from multiple external sources into the ABRC system to: create new specimen records in the ABRC database, to update/modify existing records in the ABRC database, or to cause existing ABRC database records to be marked as deleted (no longer available). The ABRC system must be capable of accepting and utilizing data from external sources using multiple methods which shall include, but may not be limited to:
    - a. Receipt and automated processing of a set of bio specimen records from an external source, consisting of selected data elements from a subset of the records contained in the source's bio



specimen database, using a regularly scheduled or specifically initiated transmission, using a standard, secure protocol, such as FTP plus SSL. Once received by the ABRC system, this data set will be processed by the ABRC software to map data elements from the host format to the ABRC database format. The ABRC software processing these data sets must have the ability to flag and exclude any incoming records that cannot be properly mapped, or which appear to be incomplete, and to generate error notices about records which were flagged so that corrective actions may be taken. This functionality should include provisions for processing both new specimen records and the updating of records for specimens already contained in the database to capture changes in status;

- b. Use of a secure, interactive ABRC data entry module/applet that allows registered users at an external source to key in the set of information about a bio specimen that is required to create a new ABRC database record, have the information checked for completeness and reasonableness by the ABRC module/applet, and update the ABRC database with the resulting information/records. This includes editing to create both new specimen records and the updating of records for specimens already contained in the database. The data editor should provide functionality to support automatic syntax formatting of data and context sensitive code lists. Data editing support within the applet at the data element level should include features such as definition of default values, suggested mapping of terms from the source vocabularies to the standard ABRC vocabulary, data normalization, categorical values, selection lists of acceptable values, min/max value limits checking (including context specific limits that are based upon entries in other data fields), etc. Validation checks should include determination of the presence of a valid value in the data field, ensuring that the entered value does not conflict with other data for that specimen, and proactive assurance that the value does not violate the referential integrity of the database.
5. Capable of generating an audit trail. At a minimum, this will entail the creation of an audit trail that captures each transaction that changes an ABRC database record (including its status), automatic time-stamping of when the change occurred, and the ID of the authorized user who made the change.
6. Capable of tracking the status of bio specimens from their collection (initial entry into the ABRC database), through distribution to a researcher, receipt by the researcher and the potential return or disposal of unused specimen material. Institutional users (entities providing the specimens) must have the ability to query for a display/report of all of their specimen records in the ABRC database which currently are in a specific status (available, pending shipment, shipped, deleted/inactive, etc.).
7. Capable of creating, storing, maintaining, modifying and deleting/deactivating institutional (external specimen sources) user accounts which are secure and role-based. Associated with each source institution's account information should be material that sets out any generalized restrictions on the use of specimens offered for use by that institution, and the ABRC software must have the ability to use those restrictions to eliminate specimens from those matching queries made by researchers working on studies which violate the conditions. The ABRC software shall allow institutional users to view the entire database of specimen records, and to create and make changes to the records for specimens belonging to/housed at their institution in the ABRC database.
8. Capable of registering specimen requesting institutions and researchers (Principle Investigators and others) and of creating and maintaining (update and cancel) role-based user accounts (institutional roles will include both those which participate as external specimen sources, and those which do not but which conduct research and will order specimens through the ABRC system). Researcher accounts will allow the user to have access to the ABRC system to browse the contents of the ABRC database, without explicitly knowing at which institution a specific bio specimen is stored, determine whether the specimen is of value to their research and the conditions of its use, request further information about the specimen, and request that the specimen be shipped to them.

9. Capable of registering and maintaining (update and cancel) approved (approval will be determined by an ABRC committee prior to the creation of a user account) research activities (studies) being conducted by registered researchers and/or institutions and capture information about the research that will enable the ABRC software to determine whether individual bio specimens represented in the ABRC database may be used in that research. Study data will include, at a minimum, the purpose of the study, study approvals by the researcher's home institution, shipping address information, designated point of contact for chain of custody maintenance, and, possibly, payment method.
10. Capable of allowing any registered researcher to browse/query the ABRC database, using criteria about his/her current or anticipated future research needs, and have the ABRC software to display information on those specimens which are currently available and which meet those criteria, and the conditions set for the use of those specimens, including any requirements for return of unused/unconsumed specimen materials. The query results will be presented without explicitly identifying the institution at which a tissue specimen is stored, but will allow the researcher to discern whether the tissue is of value to their research. Specifically, the existence of other data associated with the specimen (listed by type, i.e. clinical, tissue, pathological, gene expression data, proteomic data, characteristics regarding medications taken, treatment, longitudinal data, X-Rays, Blood tests etc.) will be noted on the ABRC record, but that information will not be stored in the ABRC database. A researcher will, however, be able to use the ABRC system to request that information, or a summarized version of it, be supplied to him before deciding whether or not to order the specimen. The ABRC system will generate a request to the source institution to generate a report, outside of the ABRC system, on the additional information associated with specific specimens selected by the researcher. That report will be shared with the researcher.
11. Capable of allowing a researcher to select specimens from among those in the ABRC database which meet his research criteria, and to request that they be shipped to him. The ABRC software must send notification to the source institution that owns the specimen about the request, including the name of the requesting PI, the study in which the specimen will be used, the institution sponsoring the study, the address to which the specimen is to be shipped, the method of payment, etc. The software must maintain a record of each shipping request in order to track the location of the specimens.
12. Capable of capturing information on when a specimen has been shipped, where it has been shipped and to whom, and when it is expected to be delivered. The ABRC specimen record will be marked as "shipped"/unavailable and will not display on any subsequent database queries made by other researchers. If the source institution has determined that it will not honor a shipping request, this result must also be captured within the ABRC system, and a denial notice generated for transmission to the requesting researcher. Shipping or denial of shipping information may be keyed in, or received as part of an update set from the source institution. The software should automatically trigger a "tickler" note if more than 14 days have elapsed from when a specimen has been requested and no update to the status of the specimen has been received. The software must also be able to capture when a specimen has been received at the requesting institution, and if it was found to be damaged upon arrival. The software should trigger an automatic tickler if more than 5 days have past since the anticipated date of delivery and no update to indicate its arrival has been posted.
13. Capable of capturing information about the disposition of any unused portion of a specimen that has been shipped to a researcher. Anticipated end states for shipped specimens would include: fully consumed in the course of the research; partly consumed or unused, with the residual being returned to the source institution; partly consumed or unused, with the residual being destroyed; damaged and unusable/destroyed. The specimen record shall be updated to mark the specimen as deleted from the database, and notice of final disposition will be shared with the source institution.
14. Capable of supporting a feedback mechanism from recipients of specimens to capture information on the quality of the bio specimen(s) received.

15. Capable of generating reports, which shall include the capability of a researcher to: capture the results of a query in a format that can be output as a file or printed; allow a source institution to obtain a summarization of the status of all or a definable subset (total specimens available, specimens shipped, specimens requested but not yet shipped, specimens shipped but not yet received, by requesting institution, by requesting researched, by specimen type, by disease type, etc.) of the records for its specimens as they exist within the ABRC database; and, allow ABRC to obtain a summarization of all specimen records by active, inactive (deleted), and by all categories supported for source institutional reporting, etc. Reports should provide either detailed information (at the individual specimen record level) or summary information (counts of records under various headings), or both. Additionally, temporal transactional reporting for all categories of users should be supported, allowing reports such as number of specimens added, modified, inactivated, shipped, returned, destroyed, etc. during a definable period of time, such as this month, the most recent month, the current quarter, the current year, last year, and so forth.
16. Fully support HIPAA, 21 CFR Part 11, and the May 2007 Guidance from the FDA on Computerized Systems used in Clinical Investigations (<http://www.fda.gov/OHRMS/DOCKETS/98fr/04d-0440-gdl0002.pdf>).

## ***Product and Vendor Information and Evaluation Sheets***

Competitive pricing must be included for all products and services needed to satisfy the Scope of Work (Section D) and Functionality Requirements (Section E), which are detailed above. This section provides a means to compare vendors' product and service offerings. Vendors will only use these sheets or facsimiles of these sheets in responding to this proposal requirement.

Respond to all of the following questions with reference to your currently available standard product. Make note of any features that will only be available in your next release and state the expected date when this release will be available. Also note if any features are handled outside of the standard product and must be purchased separately. If any additional modules are needed, or if enhancements to existing modules must be created to satisfy ABRC's stated requirements, please list the license/purchase price in the Cost/Pricing section.

### **Software Product Requirements**

Indicate the level of compliance with each requirement - fully, partly or not compliant. Explain how you will satisfy any requirements that are not marked as fully compliant.

Provide short written answers where applicable.

<b>Requirement</b>	<b>Full</b>	<b>Part</b>	<b>No</b>	<b>Comments</b>
1. HIPAA compliant				
2. 21 CFR Part 11 compliant				
3. Support May 2007 Guidance from the FDA on Computerized Systems used in Clinical Trials				
4. Secure, de-identified acquisition and storage of patient clinical and tissue data				
5. Secure, role-based views into the database of all designated institutional participants				
6. Specimen tracking from point of entry into the ABRC system through distribution, receipt and potential return of unused material.				
7. Feedback mechanism from specimen recipients on quality of specimens received and results produced.				
8. Ability for researcher to browse the specimen database without explicitly knowing which institution houses a particular specimen, but able to determine if the specimen is of value to their research and the conditions on its use.				

<b>Requirement</b>	<b>Full</b>	<b>Part</b>	<b>No</b>	<b>Comments</b>
9. Software uses web services, is portal accessible, and can support a minimum of 10 concurrent, role-based user sessions.				
10. Create, store, maintain, modify and deactivate a minimum of 500,000 bio specimen records.				
11. Unique, de-identified (HIPAA compliant) specimen record ID				
12. Automated mapping of multiple vocabularies into the standard vocabulary to be utilized for ABRC bio specimen records.				
13. Support bio specimen record data elements as listed in Section E.2 (note any elements not supported as described).				
14. Input of bio specimen information from multiple external sources via automated transmission, receipt and processing (list file transfer protocols supported, and general features of the editing/input software, with a focus on error detection and handling).				
15. Input of bio specimen information from external participants via the use of a secure, web-based interactive editing tool or module (describe the general features of the tool, with a focus on information validation, context-specific code lists, defaults and value ranges).				
16. Generation of audit trail information to capture all changes to bio specimen records.				
17. Creating, storing, maintaining, modifying and deleting/deactivating institutional (external specimen sources) secure, role-based user accounts.				
18. Creating and maintaining (update and cancel) role-based user accounts for specimen requesting institutions and researchers (Principal Investigators and others).				
19. Registering and maintaining (update and cancel) approved research activities (studies) being conducted by registered researchers and/or institutions.				
20. Capturing information about the research that will enable the ABRC software to determine whether individual bio specimens represented in the ABRC database may be used in that research.				

Requirement	Full	Part	No	Comments
21. Capable of allowing any registered researcher to browse/query the ABRC database, using criteria about his/her current or anticipated future research needs, and display information on those specimens which are currently available and which meet those criteria, and the conditions set for the use of those specimens.				
22. Allowing a researcher to select specimens from among those in the ABRC database which meet his research criteria, and to request that they be shipped to him.				
23. Generate reports which capture the results of a query in a format that can be output as a file or printed.				
24. Generate reports summarizing the status of all or a definable subset of the status of a source institution's specimen records.				
25. Generate transactional reports such as number of specimens added, modified, inactivated, shipped, returned, destroyed, etc. during a definable period of time, such as this month, the most recent month, the current quarter, the current year, or last year.				
26. Support context-sensitive, on-line help for users.				

## Hardware and Software Product Information

Please provide answers to the items below that best describe your recommended hardware (if any) and software product offering.

1. What hardware platform (size, capacity and operating system) is required for operation of the software product, and does your firm supply that hardware?
2. ABRC intends for the successful offeror to host a dedicated server and the specific version of the ABRC bio specimen tracking system software that it licenses via this contract. Therefore, please describe the costs and operational capabilities that will accrue to ABRC by using your hosting service, state the standard hours of operation of the service (e.g., normal business hours, 24 x 7, etc.), and any guaranteed or anticipated times for recovery of service in the event of a system failure. If you do not provide hosting, please describe existing arrangements with third parties currently providing hosting services for your product and the costs and any operational limitations of that service.
3. Is your software product open-source, open-architecture? Identify the language(s) used in the software.
4. What database engine(s) are utilized by your software product?
5. What connectivity standards does your product adhere to?

6. Describe your implementation of security for user sessions, including account/password assignment and logout.
7. Describe the record-locking processes used by your software product.
8. Describe the availability, if any, for database backup and restoration which are included in your software product.
9. Can third party programs be integrated with your software product? If so, please describe the limitations and processes for doing so.
10. Are there any known incompatibilities with any other software typically running on servers (backup software, firewall, virus scanning, etc.)? If so, please describe how these have been overcome for other customers.
11. Describe your process for providing training to users of your software product. If your company does not provide training directly, please describe provisions that you intend to make to obtain those services for ABRC users through a third party.
12. Describe your process for providing help desk support for users of your software product. If your company does not provide help desk support directly, please describe provisions that you intend to make to obtain those services for ABRC users through a third party.
13. Describe the general process for the implementation of your software product, and for update releases/patches to the product. How does your staff coordinate these processes with customers, such as ABRC?

## **Service and Support**

Please provide answers to the following questions about your firm's service and support:

1. Is support provided directly from your company or through a third party?
2. What are the normal hours of support availability?
3. What is the process for emergency support, outside of regular hours?
4. What is the average response time to problems? Is there a response time guarantee?
5. What are your problem determination and resolution processes and what tools are utilized?
6. What is the process used to determine the contents of a new release of your basic software product? Do customers have direct input into the process?
7. What policies or philosophies are adhered to in the creation of a new release (e.g., backward compatibility incorporated, migration/conversion modules supplied, etc.)?

## Vendor Profile

1. Provide the full name of your company, its physical address, mailing address, phone number, fax number and email contact address of your company's main office.
2. Is your company a subsidiary of another company? If so, provide the same information for the parent company as that supplied for your company in item 1.
3. Identify the person in your company who will be ABRC's primary point of contact during the proposal evaluation process. Please provide name, title, direct phone number, fax number, email address, and mailing address.
4. Identify the person in your company who is authorized to negotiate a contract with ABRC. Please provide name, title, direct phone number, fax number, email address, and mailing address.
5. Provide a brief history of your company.
6. Provide the number of years that your proposed software product has been in use, the total number of licensed customers during that time and the current number of licensed customers.
7. List any/all third party alliances made by your company which are involved in your software product or service offering, and how they are associated with your company.
8. Indicate the total number of employees in your company, the number of technical staff involved with software development of your basic product, and the number of staff dedicated to customization of product modules for your clients.
9. Indicate all certifications, such as CMMI, possessed by your company that demonstrate adherence to sustainable and repeatable software developmental processes. Note certification type, highest certification level achieved, current certification level, and date(s) when these levels were attained. Explain, briefly, how software development occurs in your company, citing specifically implementation and use of certification model principles.
10. Provide three (3) contacts at existing customers (licensees of your software product. Include customer name, contact name, contact title, customer phone number, contact direct phone number, customer fax number and contact email address.
11. Provide a copy of your most recent annual report and financial statements.



## Request for Competitive Sealed Proposals

ABRC ID#

1. TITLE OF PROJECT: Bio Specimen Tracking System Implementation and Operations

2. Proposal Copy: Original: ☐

Copy Number (1-7): \_\_\_\_

Peer Reviewer Copy: ☐

3. SUBMITTING COMPANY:

3a. MAILING ADDRESS (*Street, city, state, zip code*):

4. CONTACT PERSON AUTHORIZED TO NEGOTIATE ON BEHALF OF COMPANY

4a. NAME:

4b. TITLE:

4c. TELEPHONE (*Area code, number and extension*):

4d. FAX:

4e. E-MAIL ADDRESS:

5. PROPOSED PROJECT MANAGER

5a. NAME:

5b. TITLE:

5c. TELEPHONE:

5.d FAX:

5e. E-MAIL ADDRESS:

6. DATES OF PROPOSED PERIOD OF CONTRACT: January, 2009 through December, 2011

7. TOTAL COSTS REQUESTED FOR BUDGET PERIOD: \$

7a. Year One (\$):

7b. Year Two (\$):

7c. Year Three (\$):

8. ADMINISTRATIVE OFFICIAL TO BE NOTIFIED IF AWARD IS MADE

8a. NAME:

8b. ADDRESS:

9. OFFICIAL SIGNING FOR APPLICANT ORGANIZATION

9a. NAME:

9b. TITLE:

9c. ADDRESS :

9d. E-Mail:

9e. TELEPHONE:

9f. FAX:

10. SIGNATURE OF OFFICIAL NAMED IN 9. (*In ink. "Per" or "For" signature not acceptable.*)

APPLICANT ORGANIZATION CERTIFICATION AND ACCEPTANCE: I certify that the statements herein are true, complete and accurate to the best of my knowledge, and accept the obligation to comply with ABRC terms and conditions if a contract is awarded as a result of this proposal submission. I am aware that any false, fictitious, or fraudulent statements or claims may subject me or my institution to criminal, civil, or administrative penalties.

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

(RFP No. FY09-200)

Project Manager (Last, First, Middle): \_\_\_\_\_

### BIOGRAPHICAL SKETCH

Provide the following information for the key personnel being proposed, beginning with the Project Manager. Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME:

POSITION TITLE:

EDUCATION/TRAINING (*Begin with baccalaureate or other initial professional education, and include postdoctoral training.*)

INSTITUTION AND LOCATION	DEGREE (if applicable)	YEAR(s)	FIELD OF STUDY
--------------------------	---------------------------	---------	----------------

- 1.
- 2.
- 3.
- 4.
- 5.

**Complete the following sections.**

**A. Positions held.** List your current and previous positions in reverse chronological order, beginning with your present position. Indicate organization name (employer) organizational title and dates held, organizational responsibilities (brief job description), major project assignments, project titles or roles (if different from organizational title), responsibilities on those projects and significant achievements.

**B. Technical skills.** Highlight demonstrable technical expertise, such as training and certification.

**C. Publications.** List in reverse chronological order, by date of publication. Cite title of work, co-authors, publication name and publication date.

**D. Memberships.** List current memberships in technical societies or organizations that are relevant to your work and expertise.

## SAMPLE LETTER OF ASSURANCE

**NOTE: THE SUBMITTED VERSION OF THIS LETTER OF ASSURANCE MUST BE ON COMPANY LETTERHEAD AND SIGNED BY A PERSON AUTHORIZED TO COMMIT THE INSTITUTION TO THESE ASSURANCES.**

1. If a Contract is awarded, the **(FILL IN NAME OF INSTITUTION)** certifies that the price submitted was independently arrived out without collusion and agrees to:
  - a. Comply with the Commission's monitoring activities.
  - b. Comply with the Commission's progress and reporting requirements.
  - c. Comply with the Commission's General Provisions.
  - d. Provide services as required by the Scope of Work Statement of the Contract.
  - e. Submit with the signed Contract, proof of insurance adequate to meet the stipulations of the General Provisions of the Contract.
2. Name of Project Manager: \_\_\_\_\_
3. Telephone Number of Project Manager: \_\_\_\_\_
4. Organizational Structure (select only one type):

County Agency	Not-For-Profit Organization
Educational Institution/District	Partnership
For-Profit Corporation	Sole Proprietorship
Individual State Agency	
Municipality	Other (specify)
5. Institution's Federal Employer's Identification No. \_\_\_\_\_

\_\_\_\_\_  
Signature of Company's Authorized Officer  
indicating Approval of Proposal Submission

\_\_\_\_\_  
Date

\_\_\_\_\_  
Typed Name and Title

## CONFLICT OF INTEREST NOTIFICATION AGREEMENT

Your company has elected to submit a proposal in response to RFP09-200 which has been published by the Arizona Biomedical Research Commission (ABRC).

It is essential that the integrity of the evaluation process be maintained to insure that each offer is given fair and equal consideration. Your company may have familiarity with individuals or institutions who are affiliated with the ABRC or who may be requested to review proposals received as a result of this solicitation, and this familiarity may tend to influence the evaluation of your or other's proposals, and compromise the weighing each proposal on its merits.

You are required to report to the Executive Director any actual or potential conflict of interest so that if such a conflict exists, the individual or individuals involved will be asked to refrain from evaluating the proposal or proposals in question.

In Arizona there is a legal mandate to maintain strict security and confidentiality regarding the content of any proposal, as well as the proceedings of any peer reviewer meetings which may be held during the evaluation process. Once the evaluation process is started, you may not contact any of the staff of ABRC, any ABRC Commissioners, or any proposal reviewers, except through the Executive Director. Any contact with any of these individuals, or by any of them to you or anyone in your company, must be reported immediately to the Executive Director.

Please have an authorized representative of your organization sign the following statement:

I have read and understand the above and agree to be bound by the principals represented therein. \_\_\_\_\_  
(fill in company name) agrees to report any potential conflicts of interest and to refrain from contacting persons affiliated with ABRC during the period of proposal review. I acknowledge that recommendations regarding all proposals shall be based on the technical and scientific merits of each proposal, as presented, and any other award criteria required by the Arizona Biomedical Research Commission as presented in their solicitation.

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Signature

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Date

## Arizona Biomedical Research Commission RFP09-200

### Budget Worksheet #1

Period I: Contract Start through Implementation of ABRC Bio Specimen Tracking System

From: January 1, 2009

To:

Cost Section No.	Sub-section No.	Description	License \$	Labor \$	Labor Hrs	Equip-ment \$	Travel \$	Other \$	Total \$
1		<b>Base system price</b>							
	1	Server and related hardware							\$0
	2	Basic software product license and fees							\$0
	3	Additional software modules license and fees							\$0
2		<b>Enhancement/extension of the basic software product to fulfill ABRC requirements</b>							
	1	Discovery Phase							\$0
	2	Modify or enhance COTS software or basic service offering software to give it all of the functionality required by the ABRC software functional requirements set							\$0
	3	Establish the ABRC database model in accordance with the requirements set							\$0
	4	Define and develop the training materials and on-line help documentation that shall be delivered and installed as part of the ABRC implementation cycle							\$0
	5	Develop a test plan for the ABRC software and database system							\$0
	6	Execute the test plan iteratively to perfect the system software							\$0
	7	Execute the training curriculum according to the training schedule							\$0
3		<b>Implement and install (initiate) the system</b>							
	1	System implementation							\$0
	2	data migration							\$0
	3	user account initiation							\$0
	4	other							\$0
Totals		<b>Period I</b>	\$0	\$0	0	\$0	\$0	\$0	\$0

**Budget Worksheet #2**

**Period II: From Implementation of ABRC Bio Specimen Tracking System through End of Contract Year 1**

**From:**

**To: December 31, 2009**

Cost Section No.	Sub- section No.	Description	License \$	Labor \$	Labor Hrs	Equip- ment \$	Travel \$	Other \$	Total \$
4		<b>Provide operations and maintenance services</b>							
	1	Server operations and maintenance							\$0
	2	Connectivity							\$0
	3	Basic software product maintenance license and fees							\$0
	4	ABRC bio specimen tracking software							\$0
	5	Database							\$0
5		<b>Service and Support</b>							
	1	Help desk service							\$0
	2	Training and document support							\$0
6		Respond to reports of apparent system bugs, incorrect or missing functionality, or other deficiencies							\$0
7		Provide ABRC with all standard software upgrades							\$0
Totals		<b>Period II</b>	\$0	\$0	0	\$0	\$0	\$0	\$0

**Budget Worksheet #3**

**Period III: Contract Year 2**

**From: January 1, 2010**

**To: December 31, 2010**

Cost Section No.	Sub- section No.	Description	License \$	Labor \$	Labor Hrs	Equip- ment \$	Travel \$	Other \$	Total \$
8		<b>Provide operations and maintenance services</b>							
	1	Server operations and maintenance							\$0
	2	Connectivity							\$0
	3	Basic software product maintenance license and fees							\$0
	4	ABRC bio specimen tracking software							\$0
	5	Database							\$0
9		<b>Service and Support</b>							
	1	Help desk service							\$0
	2	Training and document support							\$0
10		Respond to reports of apparent system bugs, incorrect or missing functionality, or other deficiencies							\$0
11		Provide ABRC with all standard software upgrades							\$0
Totals		<b>Period III</b>	\$0	\$0	0	\$0	\$0	\$0	\$0

**Budget Worksheet #4****Period IV: Contract Year 3****From: January 1, 2011****To: December 31, 2011**

Cost Section No.	Sub- section No.	Description	License \$	Labor \$	Labor Hrs	Equip- ment \$	Travel \$	Other \$	Total \$
12		<b>Provide operations and maintenance services</b>							
	1	Server operations and maintenance							\$0
	2	Connectivity							\$0
	3	Basic software product maintenance license and fees							\$0
	4	ABRC bio specimen tracking software							\$0
	5	Database							\$0
13		<b>Service and Support</b>							
	1	Help desk service							\$0
	2	Training and document support							\$0
14		Respond to reports of apparent system bugs, incorrect or missing functionality, or other deficiencies							\$0
15		Provide ABRC with all standard software upgrades							\$0
Totals		<b>Period IV</b>	\$0	\$0	0	\$0	\$0	\$0	\$0



**Budget Worksheet #5**

Summary all Contract Periods

Con- tract Period	Work- sheet No.	Description	License \$	Labor \$	Labor Hrs	Equip- ment \$	Travel \$	Other \$	Total \$
I	1	Contract Start through Implementation of ABRC Bio Specimen Tracking System	\$0	\$0	0	\$0	\$0	\$0	\$0
II	2	From Implementation of ABRC Bio Specimen Tracking System through End of Contract Year 1	\$0	\$0	0	\$0	\$0	\$0	\$0
III	3	Contract Year 2	\$0	\$0	0	\$0	\$0	\$0	\$0
IV	4	Contract Year 3	\$0	\$0	0	\$0	\$0	\$0	\$0
Totals		<b>All Contract Periods</b>	\$0	\$0	0	\$0	\$0	\$0	\$0

**Budget Worksheet #6**

**Add new functionality to the ABRC system**

**Specify Labor Cost basis (e.g. \$/hour, \$/day):**

	Labor Category	Year 1	Year 2	Year 3
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				

# **REQUEST FOR COMPETITIVE SEALED PROPOSAL**

## **RFP NO. FY09-200**

### **GENERAL PROVISIONS FOR CONTRACTS**

#### **1. DEFINITIONS**

As used throughout this document, the following terms shall have the meanings set forth:

- 1.1 “ABRC” means the Arizona Biomedical Research Commission.
- 1.2 “Bayh-Dole Act” means the provisions of 35 U.S.C. §§ 200 through 212 (as amended) together with all regulations promulgated there under.
- 1.3 “Budget Request” means those provisions of the Contract that describe the specific financial amounts, payment, accounting, and substantiation requirements and arrangements of the Contract.
- 1.4 “Chairman” means the Arizona Biomedical Research Commission (ABRC) Chairman or duly authorized representative.
- 1.5 “Commission” means the Arizona Biomedical Research Commission (ABRC) or any successor in interest.
- 1.6 “Contract” means all written documents comprising the agreement of the parties, including but not limited to, these General Provisions, the solicitation, the Contractor’s proposal, the Acceptance Declination of Contract Award, Budget Requests, Budget Summaries, and budget transfer requests.
- 1.7 “Contract Material” means all written and electronic information, recordings, reports, findings, research information, abstracts, results, software, data, and any materials created, prepared, or received by the Contractor and Subcontractors in performance of this Contract.
- 1.8 “Contractor” means the person, firm, or organization performing, or accountable for performing the services or delivering the items described in this Contract.
- 1.9 “Controlling Party” means the party to this Contract is in the Best Position to

perform the duties of the Controlling Party hereunder. For purposes of this Contract, “Best Position” means the party to the Contract who has the money to fully advance the development of any Discovery, and/or the party that owns or controls a dominant patent or minor patents critical to the development of any Discovery.

- 1.10 “Cost Reimbursement” provides for reimbursement to the Contractor for actual costs incurred, as outlined in the Contract, in delivering services under the Contract.
- 1.11 “Derivative Research” means any research that was deduced or evolved from prior research and/or testing of a discovery.
- 1.12 “Derivative Work” means any work that is deduced or obtained from Contract Material or any portion thereof including, but not limited to any translation, arrangement, abridgment, recasting, transformation, or adaptation of Contract Material or any portion thereof.
- 1.13 “Development Costs” shall include only those Verifiable expenses arising solely and directly from the testing of a discovery or any derivative research thereto, evaluation of a Discovery, registration of a Discovery, obtaining or protecting a patent covering a Discovery, marketing of a Discovery (including fees or commissions payable to a third party), negotiations of contracts with third parties for licenses to make use of a Discovery, attorney’s fees for obtaining a patent, attorney’s fees for the negotiation and/or drafting of license agreements for a Discovery, and licensing of a Discovery. Verifiable expenses shall not include any allocation of indirect costs by any party.
- 1.14 “Direct payment of money to the research being performed hereunder” means those payments of money made directly to the research being performed under this Contract solely for the purpose of completing that research and the term shall not include any indirect payments or administrative costs. In calculating a party’s direct payment of money to the research being performed hereunder, the party may include amounts of salaries and benefits proportionate to the amount of time devoted by an employee directly to the research being performed hereunder, and funds that it receives from outside grants and other sources that the party pays directly to the research being performed under this Contract solely for the purpose of completing that research.
- 1.15 “Discovery” means any discovery, invention, or resulting patent(s) that arise(s) from research carried on by or under the direction of the Contractor in performance of this Contract.
- 1.16 “EDA” means effective date of Amendment.
- 1.17 “Executive Director” means the person designated to represent the Commission in

the program administration of this Contract.

- 1.18 “Gross Income” means the total revenue received by the Controlling Party from the manufacture, use, lease, or sale of title to a Discovery or license to use thereof or any amounts attributable thereto, including the fair market value of any in-kind compensation.
- 1.19 “Management Fees” means fees for expenses of maintenance of a Discovery and administrative costs arising from the accounting and reporting required under this Agreement. Management Fees shall be paid only from Net Income received after all Development Costs of both parties have been fully reimbursed. Management Fees shall not exceed ten percent (10%) of the Net Income received.
- 1.20 “Net Income” means the Gross Income received by the Controlling Party less all Development Costs.
- 1.21 “Net Net Income” means the Gross Income received by Controlling Party less:
  - 1.21.1 All Development Costs;
  - 1.21.2 Management Fees; and
  - 1.21.3 All other amounts agreed to be excluded by prior written approval of both parties.
- 1.22 “Outside Funding” means all funding for the work to be conducted by the Principal Investigator under this Contract that does not come from the Contractor and shall include internal monetary awards from the Contractor over which the Principal Investigator has exclusive control.
- 1.23 “Principal Investigator” means a person or entity who provides services or materials pursuant to the Contract in the nature of a developer, inventor, or researcher, usually requiring special skill and advanced education of a mental and intellectual nature. A Principal Investigator is usually a person who is an employee or agent of the Contractor, but a Principal Investigator could also be an entity, the Contractor, or a Subcontractor. A Contract may involve more than one Principal Investigator.
- 1.24 “Professional acts” means services or acts of persons whose vocation or occupation requires special, usually advanced, education and skill which is predominantly mental or intellectual rather than physical or manual.
- 1.25 “Reporting Period” means one of the two Reporting Periods during each calendar year. The first Reporting Period of the calendar year shall run from the first business

day of each calendar year to the last business day in June. The second Reporting Period of each year shall run from the first business day in July to the last business day in December.

- 1.26 “Shall” means what is mandatory.
- 1.27 “State” means the State of Arizona including the Commission, and shall not, for purposes of this contract, include the Contractor.
- 1.28 “Subcontract” means any Contract between the Contractor and a third party to provide or be accountable for providing all or a specified part of the services or items which the Contractor has himself contracted with the Commission to provide.
- 1.29 “Verifiable” means evidenced by true and complete copies or originals of bills, invoices or the like and similar evidence of payments of such bills, invoices or the like.
- 1.30 “Work Statement” means those provisions of this Contract which delineate the scope and manner of the specific services to be performed and/or describe the items to be supplied in the performance of this Contract. If the provisions of the Work Statement conflict with the General Provisions, the terms of the Work Statement shall govern.

## **2. GENERAL REQUIREMENTS**

- 2.1 The Contract Term is the date identified by the Commission as the start and end date of the Contract or Amendment. The Contract Term may begin before the Contract or Amendment is fully executed by the parties or at a later date as specified therein. The Contractor shall not bill the Commission for costs incurred under this contract or Amendment until the Contract or Amendment is fully executed. The Contractor may however, at the Contractor’s own risk begin work on the Contract or Amendment and may incur allowable expenditures following the Contractor’s receipt of written notification of the Commission’s determination to award or extend the Contract or Amendment. The written notification shall contain an identified Contract Term in the notification.
- 2.2 The effective date of the Contract or Amendment is the date the Contract or Amendment is signed by all parties.
- 2.3 The Contractor, unless otherwise exempt by law, shall obtain and maintain all licenses, permits and authority necessary to do business and render services under this Contract.
- 2.4 The parties hereto agree that the Contractor is an independent Contractor in the performance of this Contract and is not an officer, employee or agent of the Commission.

- 2.5 Except for persons employed by the Arizona Board of Regents, or units thereof, no individual employed by the State shall have a substantial interest in this Contract or receive a substantial benefit that may arise there from.
- 2.6 Contractors receiving State funds under this Contract shall comply with the certified financial and compliance audit provisions of A.R.S. § 35-181.03.
- 2.7 If matching funds are required to receive an award of this Contract, matching funds should be met with currency or cash equivalents, unless otherwise specified. The Commission may elect to authorize limited in-kind matches on a case by case basis. Release time for clinicians will be considered as a component of the Contractor match. Salary limits and other information describing allowable release time for purposes of the match can be found in the instructions for the budget.

### **3. OTHER CONTRACTS**

The Commission may authorize additional work related to this Contract or award other Contracts for such work. The Contractor shall cooperate reasonably with such other Contractors and/or State employees in scheduling and coordinating its work with such additional work. The Contractor shall afford other Contractors reasonable opportunity for the execution of their work and shall not commit or permit any act which will unreasonably interfere with the performance of work by any other Contractor or by State employees. The Commission shall equitably enforce this Section as to all Contractors to prevent unreasonably burdening any Contractor.

### **4. SUBCONTRACTS AND ASSIGNMENTS**

- 4.1 The Contractor shall not subcontract with any other person or entity to provide or account for any service or item required by this Contract unless (a) the subcontract was already part of the proposal or (b) the Commission has provided the Contractor with prior written approval.

- 4.2 If Subcontracts are permitted hereunder, the Contractor agrees to use written Subcontracts which conform to Federal and State laws and regulations appropriate to the service or activity covered by the Subcontract, and which are consistent with the terms of this Contract.
- 4.3 The Contractor is responsible for the actions and performance of any Subcontractor. The Contractor is also responsible for Contract performance without regard to whether Subcontractors are used.
- 4.4 The Contractor shall submit a complete copy of each proposed Subcontract with all attachments and proposed amendments to the Commission for its prior approval. Upon approval by the Commission and the execution of the Subcontract, the Contractor shall submit a complete copy of each Subcontract with all attachments to the Executive Director within fifteen (15) business days of its effective date.
- 4.5 The Contractor's rights or obligations under this Contract shall not be assigned without the prior written consent of the Commission. It shall be deemed to be a assignment without approval if, without the prior written approval of the Commission: (i) more than fifty percent (50%) of the voting control of the Contractor has been or will be transferred to third parties within a twelve (12) month period or (ii) more than fifty percent (50%) of the equity ownership in the Contractor has been or will be transferred to third parties within a twelve (12) month period.
- 4.6 The Contractor and all subcontractors shall agree that if, at anytime while this Contract is in effect, they or any one of them acquire or have acquired patents, rights, or interests in a patent that dominates over a Discovery that arises under this Contract, the Contractor or subcontractor that so acquired or acquires will notify the Commission within thirty (30) days of learning of a dominating patent and will cooperate fully with the Commission if it so requests in order to protect any interest in or with respect to the Discovery that belongs to or is to be received, in whole or in part, by the Commission pursuant to the Contract.

## **5. OWNERSHIP OF INTELLECTUAL PROPERTY**

- 5.1 It is the intent of the Commission that all intellectual property developed under this Contract be used and controlled in ways to produce the greatest benefit to the parties to this Contract, the inventor, the inventor's parent institution, and the citizens of the State of Arizona.
- 5.2 Copyrights and Research Information
  - 5.2.1 Title and exclusive copyright to all Contract Material shall vest solely in the Controlling Party. Each party to this Contract shall execute all documentation requested by the Controlling Party for the purpose of securing for the Controlling Party all interests in and to all copyrights to the Contract Material.
  - 5.2.2 Each party to this Contract that is not the Controlling Party shall have full, complete, perpetual, irrevocable and nontransferable rights to reproduce, duplicate, adapt, make Derivative Works, distribute, display, disclose, publish, and otherwise use all Contract Material. The Controlling Party may, at its option, and in its sole discretion, hold, sell, or otherwise dispose of its title or any lesser right or interest to any Contract Material. If the Controlling Party declines to take title to the Contract Material or desires to transfer title of



the Contract Material to a third party, the other party to this Contract shall have the first right of refusal to take title to that Contract Material and act as the Controlling Party hereunder.

- 5.2.3 Prior to any presentation or publication, the Contractor shall notify the Commission of the date, time and location of any planned publication and forward to the Commission a copy of any Contract Material or Derivative Works including, but not limited to, manuscripts, abstracts, presentations, illustrations, tables, and photographs accepted for publication prior to the publication release date. Contract Material that contains proprietary or confidential information, sent to the Commission for review, shall be kept confidential to the extent permitted by law. Neither party shall release confidential information to the public without the prior express written permission of the other or pursuant to subpoena or court order.
- 5.2.4 Unless otherwise required by law, neither party shall release draft, interim, incomplete, or unfinished Contract Material to the public received from, or concerning any ongoing research project.
- 5.2.5 The Contractor shall give recognition to the Commission for its support of the research project when publishing Contract Material, Derivative Work, or releasing research project related public information.

### 5.3 Discoveries

- 5.3.1 Except as provided in section 5.7 below, title to and the exclusive right to patent any Discovery resulting from research carried on by or under the direction of the Contractor in performance of this Contract shall vest solely in the Controlling Party. Each party to this Contract shall execute all documentation requested by the Controlling Party for the purpose of securing for the Controlling Party all rights (including but not limited to the right to patent), titles, and interests in and to such Discovery in the United States and in all foreign countries or jurisdictions. If the Controlling Party declines to take title or desires to transfer title of the Discovery to a third party, the other party to this Contract shall have the first right of refusal to take title to that Discovery and act as the Controlling Party hereunder.
- 5.3.2 Each party to this Contract that is not the Controlling Party shall have full, complete, perpetual, irrevocable, and nontransferable rights to duplicate, produce, and otherwise use any Discovery. The Controlling Party may, at its option, and in its sole discretion, hold, sell, or otherwise dispose of its title or any lesser right or interest to any Discovery. No less than ten (10) business days prior to any transfer of title or any lesser interest in a Discovery, the Controlling Party shall notify all other parties of the proposed transfer and provide copies of the operative transfer documents to the other parties. The Controlling Party may evaluate, patent, or license any Discovery using its own resources or may make an agreement with the other party to this Contract, third party, or patent management organizations to undertake such activities.
- 5.3.3 The Contractor shall require each Principal Investigator and other persons involved in the research hereunder to promptly (defined as no later than 30 days after discovery) disclose all Discoveries made hereunder to the Commission and to a designated Contractor representative. Within 60 days of the parties' receipt of the disclosure and any supporting documentation, the parties shall mutually determine which party shall be the Controlling

Party.

- 5.3.4 The Controlling Party will be responsible for all actions or decisions related to the Discovery. The Controlling Party may take one or more of the following actions relating to the Discovery:
  - 5.3.4.1 transfer, license, or assign the Discovery or any interest in the Discovery outright to the discoverer or inventor.
  - 5.3.4.2 transfer, license, or assign the Discovery or any interest in the Discovery to one or more institutions or patent management organizations for patent and/or commercial development;
  - 5.3.4.3 evaluate the Discovery for commercial potential by a third party;
  - 5.3.4.4 license or assign the Discovery or any interest in the Discovery to any other party to this Contract for patent management or development; or
  - 5.3.4.5 patent the Discovery and then license or assign the Discovery to any other person or entity for commercialization.
- 5.3.5 The Controlling Party shall not grant or sell a license or any other interest in a Discovery unless the other party to this Agreement has been given a minimum of 30 days written notice prior to the grant or sale.
- 5.4 Within sixty (60) days of receipt of any Gross Income from the sale, transfer, or licensing of any Contract Material or any copyright thereto or any Discovery or patent thereto, the Controlling Party shall reimburse each party their respective Discovery Costs, Management Fees, and distribute their shares of the Net Net Income as described in section 5.5 below.
- 5.5 For sections 5.2 and 5.3, within forty-five (45) days of the receipt of Gross Income, the Controlling Party shall distribute the Gross Income in the following order and in accord with the following:
  - 5.5.1 The Controlling Party shall reimburse each party to this Agreement for all accrued Development Costs. The Controlling Party shall distribute reimbursements of Development Costs between itself, and all other parties to the extent possible. If sufficient funds are not available to pay all Development Costs in full, the Gross Income shall be distributed pro rata to each party. Before paying any Management Fees or distributing any Net Net Income, the Controlling Party shall first pay all accrued Development Costs of all parties.
  - 5.5.2 The Controlling Party may, at its discretion, take a Management Fee not to exceed ten percent (10%) of the Net Income received. The Management Fees distributed to the Controlling Party shall not exceed ten percent (10%) of the Net Income. Management Fees shall be reimbursed only after all of the accrued Development Costs of all parties have been reimbursed in full. The Commission may adopt a percentage Management Fee equal to that elected by the Contractor or taken by the Contractor acting as Controlling Party on other projects.

- 5.5.3 The Controlling Party shall pay all of the Net Net Income equally to each party unless the parties agree otherwise in writing. Net Net Income may be distributed only after all of the accrued Development Costs of all parties have been fully reimbursed and the applicable Management Fees have been paid.
- 5.5.4 In the event that a share of Net Net Income is received by the Commission pursuant to section 5.5, a portion of that share of Net Net Income received by the Commission shall be paid to the individual(s) who created that intellectual property as additional consideration for his, her, or their creative efforts. This portion is to be determined by the commission considering individual institutional policy, recommendations from patent management organizations or any other knowledgeable source, and other relevant factors. In no event will the inventor or inventors collectively, be awarded less than 25 percent of the share of Net Net Income provided to the Commission.
- 5.6 Within thirty (30) days after the end of each Reporting Period, the Controlling Party shall account to each party in writing for all Gross Income received during that Reporting Period and all distributions there from. At that same time, each party to this Agreement shall report to the other all outstanding Development Costs that it has incurred under this Agreement.
- 5.7 If the Bayh-Dole Act applies to a Discovery made hereunder, and the Commission would otherwise be the Controlling Party hereunder, the party that is the “contractor” under the Bayh-Dole Act shall have title to the Discovery. Within sixty (60) days of the Commission’s receipt of written notice in section 5.3.3, the Commission may make written request for and the Contractor shall make an application to the Federal funding agency and/or the United States Department of Commerce as provided in the Bayh-Dole Act for permission to transfer the title to such Discovery or resulting patent to the Commission. The Commission shall approve the form of the application before it is submitted. The Commission shall be informed promptly of any subsequent communications with the Federal funding agency and/or the United States Department of Commerce regarding the request. If the Federal funding agency and/or the United States Department of Commerce does not grant permission for the transfer: (1) the Commission shall, nevertheless, have the rights to its share of Gross Income as described in 5.5, and (2) the Contractor shall then assume the responsibilities and authorities of the Controlling Party or license the Discovery to the Commission for purposes of commercial development. In all circumstances, and without regard to whether the Commission has requested the transfer of title or patent rights or whether the Federal funding agency and/or the United States Department of Commerce has approved any such transfer, the Commission shall retain its right to share in the distribution of Gross Income as described in section 5.5 above.

## **6. CONFIDENTIALITY**

- 6.1 The Contractor, its Principal Investigators, employees, and authorized agents engaged in work under this Agreement may present at symposia or professional meetings and publish in journals, theses or dissertations, or otherwise of their own choosing, methods and Contract Material. The Contractor agrees to submit manuscripts of proposed publications to the Commission and all other parties prior to publication for review to ascertain that no confidential or proprietary information has been inadvertently disclosed by the proposed manuscript. The Contractor shall delay publication for no less than thirty (30) days to allow the parties to review the manuscript. If the parties determine that

confidential or proprietary information may be disclosed, the Contractor shall further delay publication for a time period necessary to allow the parties to protect their interests.

- 6.2 Except as provided in Sections 5.2.3 and 6.1, the Contractor shall not disclose any Contract Material any third party without the Commission's prior written consent, which shall not be unreasonably withheld.
- 6.3 To accomplish the work under this Agreement, the Commission may disclose information to the Contractor that it considers confidential. The Commission agrees to disclose only information necessary to the work and to clearly mark as "Confidential Information" any information it considers confidential. The Commission will send Confidential Information in writing only to the Principal Investigator or orally disclose it to the Principal Investigator and reduce it to writing within thirty (30) days of disclosure. The Contractor and the Principal Investigator agree, to the extent permitted by law, that Confidential Information will remain the property of the Commission and, for 5 years from the end of this Agreement, Confidential Information will not be used or disclosed to others except in furtherance of this Agreement. This obligation of non-use and non-disclosure will not apply to any portion of the Confidential Information that: (1) was known to the Principal Investigator before disclosure by ABRC; (2) is disclosed to the Principal Investigator by a third party; or (3) is or becomes known to the public through no fault of the Principal Investigator.

## **7. CONFIDENTIALITY OF PERSONAL HEALTH INFORMATION AND MEDICAL RECORDS**

- 7.1 The Contractor warrants that it is familiar with the requirements of HIPAA and will comply with all applicable HIPAA requirements in the performance of this Contract. Contractor agrees to notify the Commission of any HIPAA related concerns arising under the performance of this Contract, and will cooperate with the Commission in any HIPAA related inquiries.
- 7.2 The Contractor shall be in compliance with all Federal and State law requirements regarding the handling and disclosure of confidential medical/health information and records. No medical information contained in Contractor's records or obtained from the Commission or from others in carrying out its functions under this Contract shall be used or disclosed by Contractor, its agents, officers, employees or Subcontractors except as lawfully allowed and that such disclosure is essential to the performance of duties under this Contract. Disclosure to the Commission is deemed essential to the performance of duties under this Contract. Medical information, names, or other information regarding any person applying for, claiming, or receiving items or services contemplated in this Contract, or any employer of such person shall not be made available for any political or commercial purpose. Information received from a Federal or State agency or from any person or provider acting under the Federal or State agency pursuant to Federal or State law, shall be disclosed only as provided by Federal or State law.

## **8. RECORDS**

- 8.1 Contractors who submit cost or pricing data as provided in A.R.S. §41-2543 shall maintain books and records which reflect that cost or pricing data under the Contract and shall reflect the Contract services and expenditures. All books and records shall be maintained in accordance with Generally Accepted Accounting Principles (GAAP).
- 8.2 Contractor further agrees:
  - 8.2.1 To timely submit all accurate and complete reports and invoices as specified in the Work Statement of this Contract. Contractor and Subcontractor understand that the failure to timely submit required accurate and complete documents in the performance of this Contract may be grounds to withhold payments otherwise due or may result in termination of the Contract.
  - 8.2.2 The Contractor and any Subcontractors shall preserve and make available to the Commission and its auditors all records for a period of five (5) years from the date of final payment under this Contract and for such period as is required by any other paragraph of this Contract including the following:
    - 8.2.2.1 If this Contract is completely or partially terminated, the records relating to the work terminated shall be preserved and made available for a period of five (5) years from the date of any such termination.
    - 8.2.2.2 Records that relate to disputes, litigations or the settlement of claims arising out of the performance of this Contract or to cost and expenses of this Contract to which exception has been taken by the Executive Director shall be retained by the Contractor until such appeals, litigations, claims or exceptions have been finally resolved.
    - 8.2.2.3 If requested, the Contractor shall submit such records relating to the Contract to the address specified by the Executive Director.

## **9. INDEMNIFICATION AND INSURANCE**

- 9.1 Unless the Contractor is insured pursuant to A.R.S. §§ 41-621, *et seq* the Contractor shall at all times indemnify, defend and save harmless the Commission and/or any of its agents, officials and employees from any and all claims, demands, suits, actions, proceedings, loss, cost and/or damages of every kind and description including any attorney's fees and/or litigation expenses brought or made against or incurred by the Commission on account of loss of or damage to any property or for injuries to or death of any person, caused by, arising out of, or contributed to, in whole or in part, by reasons of any act, omission, professional error, fault, mistake, or negligence of the Contractor, its employees, agents, representatives, or Subcontractors, their employees, agents, or representatives in connection with or incident to the performance of this contract or arising out of Worker's Compensation claims, Unemployment Compensation claims, or Unemployment Disability Compensation claims of employees of the Contractor and/or its Subcontractors or claims under similar such laws or obligations. The Contractor's obligation under this paragraph shall not extend to any liability caused by the sole negligence of the Commission or its employees.

- 9.2 The Contractor shall comply with all laws regarding unemployment insurance and worker=s compensation.
- 9.3 The Contractor shall provide and maintain liability insurance as described below or liability coverage from the Arizona Department of Administration Risk Management Division to cover all actions of the Contractor, any Subcontractor, and their employees, agents, or representatives. In no event shall the total coverage be less than the minimum insurance coverage specified below:
- 9.3.1 Comprehensive general liability insurance with a minimum combined single limit of two million dollars (\$2,000,000) each occurrence. The policy shall include coverage for bodily injury, broad form property damage, (including completed operations), personal injury (including coverage of Contractual and employee acts), blanket Contractual, Contractor's protective, sudden and accidental pollution, products and completed operations.
- 9.3.2 Comprehensive automobile liability insurance with a combined single limit for bodily injury and property damage of not less than two million dollars (\$2,000,000) each occurrence with respect to Contractor's vehicles (whether owned, hired, non-owned), assigned to or utilized in the performance of this Contract.
- 9.3.3 Professional liability insurance with a minimum combined single limit of two million dollars (\$2,000,000) for each occurrence if professional acts shall be required in the performance of this Contract.
- 9.4 The Contractor shall name the State of Arizona, its agents, officials and employees as additional insured's and shall specify that the insurance afforded by the Contractor shall be primary insurance and any insurance or self-insurance of the State, the Commission or its employees shall be excess, not contributory insurance, to that provided by the Contractor. Said policy shall contain a severability of interests provision. Such policy(ies) shall contain a requirement that the insurer notify the Commission promptly of any change in coverage terms or amounts, in advance of a lapse or cancellation of coverage, or of failure to pay premium when due.
- 9.5 Contractor's failure to procure and maintain the required liability insurance or to provide proof thereof to the Commission within thirty (30) days following the commencement of a new policy period, shall constitute a material breach of the Contract upon which the Commission may immediately terminate this Contract. Prior to the effective date of this Contract, the Contractor shall furnish the Commission with copies of the State of Arizona Certificate of Insurance (RM7200.1) drawn in conformity with the above insurance requirements. The State of Arizona reserves the right to request and receive certified copies of any or all of the above policies and/or endorsements.

## **10. CERTIFICATIONS**

The Contractor certifies and agrees to provide proof that all services shall be performed in conformity with the requirements of this Contract and by qualified personnel in accordance with generally recognized standards in the biomedical research community and industry. The Commission must approve all certifications relating to animal or human research.

Contractor acknowledges that the Principal Investigator is critical to the performance of this contract and

certifies that the named Principal Investigator will be responsible for the work performed. The Contractor shall notify the Commission of any changes in the status of the Principal Investigator under this contract.

## **11. AMENDMENTS**

- 11.1 No condition, requirement or alteration contained in or made a part of this Contract shall be waived or modified without an approved, written amendment to this Contract. Amendments shall be effective only if in writing and signed by all parties.
- 11.2 Any request for an amendment shall be in writing, shall be delivered in person, courier or U.S. mail and shall be directed to the persons and addresses specified herein.

## **12. DISPUTES**

- 12.1 In the event of a dispute under this Contract, the parties agree to make a good faith attempt to resolve the dispute prior to taking formal action.
- 12.2 If the dispute cannot be resolved pursuant to Subsection 12.1 above, the dispute shall be resolved in an administrative hearing pursuant to A.R.S. § 41-2615 and A.A.C. R2-7-901, *et seq.*
- 12.3 This Contract shall be construed in accordance with Arizona law and any legal action thereupon shall be initiated in the State of Arizona.

## **13. TERMINATION OF CONTRACT**

The Commission, the State or Contractor may terminate this Contract under the following conditions:

- 13.1 The Commission, in addition to other rights set forth elsewhere in the Contract, may terminate this Contract in whole or in part without cause effective thirty (30) days after mailing written notice of termination by certified mail, return receipt requested to the Contractor.
  - 13.1.1 In the event of termination as provided in this Section, the Contractor shall stop all work as specified in the notice of termination and immediately notify all Subcontractors in writing to do the same.
  - 13.1.2 The Contractor shall be paid the Contract price for all services and items completed up to the date of termination. In addition, the Contractor will be paid its reasonable actual costs for work in progress as determined by GAAP up to the date of termination. Upon such termination, the Contractor shall deliver to the Commission a complete set of all documents, programs and other information prepared in performance of the Contract.
- 13.2 The Commission may terminate this Contract in whole or in part if, during the term of this Contract, the Contractor is listed on the Master List of debarments, suspensions and voluntary exclusions maintained pursuant to A.A.C. R2-7-933. In such case, the Executive Director shall transmit written notice of termination to the Contractor by certified mail, return receipt requested, and this Contract shall be terminated effective upon receipt thereof by the Contractor or such later date as is specified in the notice. In the event the Executive Director terminates this Contract in whole or in part as

provided in this Subsection, all subsections of this Section 13 are incorporated into this Subsection by reference and shall apply to the same extent as if expressly set out herein.

- 13.3 The Commission may terminate this Contract by written notice to the Contractor if it is found by the Executive Director after notice and opportunity for a hearing that gratuities in the form of entertainment, gifts, or otherwise were offered or given by the Contractor or any agent or representative of the Contractor to any officer or employee of the State with a view toward securing a Contract or securing favorable treatment with respect to the awarding or amending or the making of any determinations with respect to the performing of such Contract.
- 13.4 Pursuant to A.R.S. §38-511 the Commission or any other agency of the State may, within three (3) years after its execution, cancel this Contract without penalty or further obligation by the Commission or such other State agency if any person significantly involved in initiating, negotiating, securing, drafting or creating this Contract on behalf of the Commission or such other State agency is, at any time while the Contract or any extension of the Contract is in effect, an employee or agent of any other party to the Contract in any capacity or a consultant to any other party of the Contract with respect to the subject matter of the Contract. Cancellation under this subsection shall be effective when written notice from the Commission or such other State agency is received by all other parties to the Contract unless the notice specifies a later time. In addition to the right to cancel this Contract as provided in this Subsection, the Commission or such other State agency may recoup any fee or commission paid or due to any person significantly involved in initiating, negotiating, securing, drafting or creating this Contract on behalf of the Commission or such other State agency from any other party to this Contract arising as the result of this Contract.
- 13.5 This Contract may be terminated by mutual written agreement of the parties specifying the termination date therein.
- 13.6 If monies are not appropriated or otherwise made available to support continuation of performance in a subsequent fiscal period, the contract shall be canceled without any further obligation upon the Commission or State.
- 13.7 The Commission may, at any time, by written order to the Contractor, require the Contractor to stop all or any part of the work called for by this Contract for a period of ninety (90) calendar days after the order is delivered to the Contractor. The order shall be specifically identified as a stop work order issued under this clause. Upon receipt of a stop work order, the Contractor shall immediately cease all work being performed hereunder and take all reasonable steps to minimize the incurrence of costs allocable to the work covered by the stop work order during the period of work suspension. The Commission may, in its sole discretion, extend for ninety (90) days the term of or cancel a stop work order at any time. If the Commission cancels a stop work order or the period of a stop work order or any extension thereof expires, the Contractor shall promptly resume work. If the Commission issues a stop work order, the Commission shall make an equitable adjustment in the performance schedule and the Contract shall be amended accordingly.
- 13.8 The Commission may terminate this Contract upon the failure of the Contractor to cure a default under this Contract. The Commission may also terminate this Contract if the Contractor demonstrates a pattern of noncompliance, regardless of whether the defaults are ultimately cured.



## 14. DEFAULT

- 14.1 The Commission, in addition to other rights set forth elsewhere in the Contract, may by written notice of default require that the Contractor cure any default within a period of time specified by the Commission in the notice of default. Upon receipt of a notice of default, the Contractor shall promptly send written acknowledgment of receipt of the notice of default to the Commission. If the Contractor fails to cure the default within the time period specified in the notice of default, the Commission may terminate this Contract in whole or in part if the Commission determines that the Contractor has failed to perform any requirement.
- 14.2 The Contractor shall continue the performance of this Contract to the extent not terminated.
- 14.3 In the event the Commission terminates this Contract in whole or in part as provided in this Section, the Commission may procure, upon such terms and in such manner as deemed appropriate, services similar to those so terminated, and unless the Contractor is a governmental agency, instrumentality or subdivision thereof, or Indian tribe, it shall be liable to the Commission for any excess costs incurred by the Commission in obtaining such similar services.
- 14.4 Except with respect to defaults of Subcontractors, the Contractor shall not be liable for any excess costs if the failure to perform the Contract arises out of causes, natural and unnatural, that are unanticipated and beyond the control and which occur without the fault or negligence of the Contractor. Such causes may include, but are not restricted to, acts of God or of the public enemy, acts of the State or Federal Government in either their sovereign or contractual capacity, fires, floods, epidemics, quarantine restrictions, strikes, freight embargoes, unusually severe weather, unanticipated loss of personnel, unanticipated changes in availability of patient populations, and unanticipated equipment malfunctions. If the failure to perform is caused by the default of Subcontractor, and if such default arises out of causes beyond the control of both the Contractor and Subcontractor and without the fault or negligence of either, the Contractor shall not be liable for any excess costs for failure to perform, unless the services to be furnished by the Subcontractor were obtainable from other sources in sufficient time to permit the Contractor to meet the required delivery schedule.
- 14.5 If this Contract is terminated as provided herein, the Commission, in addition to any other rights provided in this Section, may require the Contractor to transfer title to and deliver to the Commission or its successor or assigns, in the manner and to the extent directed by the Commission, such partially completed reports or other documentation as the Contractor has specifically produced or specifically acquired for the performance of such part of the Contract as has been terminated consistent with Section 5 herein. Payments for completed reports and other documentation delivered to and accepted by the Commission shall be at the Contract price. Payment for partially completed reports and other documentation delivered to and accepted by the Commission shall be in an amount agreed upon by the Contractor and the Commission.
- 14.7 The rights and remedies of the Commission enumerated in this Section shall be in addition to any other rights and remedies provided by or under this Contract by law.

## **15. NON-DISCRIMINATION**

The Contractor shall comply with State Executive Order No. 99-4 and A.R.S. §§41-1461 *et seq.*, which mandate that all persons, regardless of race, color, religion, sex, age, national origin or political affiliation, shall have equal access to employment opportunities. The Contractor shall comply with all other applicable federal and state employment laws, rules and regulations, including the Americans with Disabilities Act. The Contractor shall take affirmative action to ensure that applicants for employment and employees are not discriminated against due to race, creed, color, religion, sex, national origin or disability.

## **16. ASSIGNMENT OF OVERCHARGES**

The Contractor, the Commission and the State recognize that in actual economic practice overcharges resulting from antitrust violations are in fact borne by the purchaser. Therefore, the Contractor hereby assigns to the Commission and the State any and all claims for such overcharges.

## **17. CONTRACT PAYMENTS**

- 17.1 Payments made by the Commission to the Contractor pursuant to this Contract are conditioned upon the availability to the Commission of funds authorized for expenditure in the manner and for the purpose herein. The Commission shall not be liable for any purchases or Subcontracts entered into by the Contractor in anticipation of such funding.
- 17.2 Payments made by the Commission to the Contractor are conditioned upon receipt of timely, accurate, and complete reports to be submitted by the Contractor. The Commission will pay the Contractor within sixty (60) days of receipt of timely, accurate, and complete reports.
- 17.3 If the Contractor is in any manner in default in the performance of any obligation under this Contract, or if audit exceptions are identified, the Commission may, at its option and in addition to other available remedies, either adjust the amount of payment or withhold payment until satisfactory resolution of the default or exception. The Contractor shall have the right to written notice of the Commission's action in adjusting the amount of payment or withholding payment. Under no circumstances shall the Commission authorize payments to the Contractor that exceed an amount specified in the Contract without an approved written amendment to the Contract. The Commission may, at its option, withhold payments or terminate the contract for failure to file required reports or until all final reports and deliverables are received.
- 17.4 Contractor shall not have discretion under this Contract to carry-over funds or services delivery from one state fiscal year to a subsequent state fiscal year. Contract continuation is subject to the following conditions:
  - 17.4.1 Availability of funds; and
  - 17.4.2 Demonstration of sufficient progress toward Contract goals and objectives of the research as set forth in the Proposal or Work Statement; and
  - 17.4.3 Work Statement and Contract rates negotiated and agreed to by both parties.
- 17.5 Under any extension of work authorized under section 14.4, the Contractor shall submit all revised

requests for payment during the extension period.

- 17.6 The Commission will not authorize a revised expenditure report unless the Contractor has submitted such report to the Commission on or before June 1 of the year following the year to which the revision applies.

## **18. RECOUPMENT OF CONTRACT PAYMENTS**

### **18.1 Unacceptable Expenditures**

The Contractor shall reimburse the Commission for all Contract funds expended which are determined by the Commission or the Auditor General not to have been disbursed by the Contractor in accordance with the terms of this Contract.

### **18.2 Contracted Services**

18.2.1 If the services to be performed as described in this Contract are materially less than one hundred percent (100%) of the services required hereunder, funds to be returned to the Commission will be determined by multiplying the unit of service cost as listed in the Budget Requests by the number of services which are below the one hundred percent (100%) requirement.

18.2.2 If the number of services provided in any service name is less than the services for which the Contractor received compensation, funds to be returned to the Commission shall be determined by multiplying the unit of service cost as listed in the Budget Requests by the number of services Contractor did not provide during the budget term.

### **18.3 Refunds**

The Contractor shall, within forty-five (45) days of termination, refund the greater of the amount refundable in accordance with Subsection 17.2 hereof (Contracted Services).

## **19. MANAGEMENT OF FUNDS**

For all Contracts, the practices, procedures and standards specified in and required by the Accounting and Auditing Procedures Manual for Arizona Department of Administration Funded Programs shall be used by the Contractor in the management of Contract funds and by the Commission when performing a Contract audit. Funds collected by the Contractor in the form of fees, donations and/or charges for the delivery of these Contract services shall be accounted for in a separate fund.

## **20. ALLOWABLE EXPENDITURES**

Expenditure of funds advanced, or qualifying for reimbursement, pursuant to this Contract shall be made by the Contractor only for the following:

- 20.1 Services or material approved or appropriated for, and used in, the performance of services herein agreed to be provided.

- 20.2 Services or materials which are received by the Contractor:
- 20.2.1 During the Contract term for which the funds are made available; and
  - 20.2.2 On or after the effective date of the Contract or, with regard to funds made available during a Contract term by an amendment to the Contract, on or after the effective date of that amendment; and
  - 20.2.3 On or before the termination date.
- 20.3 Dollar amounts approved in the account classifications shown on the annual Budget Summary Page of this contract may be adjusted within ten percent (10%) of the original amount shown provided that the total amount of the contract shown on the Budget Summary Page remains unchanged. Adjustments shall be made in accordance with the following:
- 20.3.1 The Contractor and Principal Investigator may reassign funds within the personnel category without requesting a change in writing so long as personnel are not being added or replaced. If key personnel are being added or replaced, the request must be made in writing. Approval by the Executive Director of the requested change constitutes a contract amendment.
  - 20.3.2  
Th  
e salary limits for Principal Investigators shall not be exceeded.
  - 20.3.3 The Contractor and Principal Investigator may reassign funds without restriction from one category to another among all other categories in which funds have been approved except Personnel and Equipment. In order to reassign funds from Personnel or Equipment to any other category or reassign funds from any other category to Personnel or Equipment, the Contractor must make a written request to the Executive Director for such reassignment and the Executive Director must approve the request in writing
  - 20.3.4 The Contractor shall submit a written request to the Commission for approval before the Contractor may reassign funds to a category in which no funds were approved in the annual Budget Request.

## **21. VISITATION AND INSPECTION**

- 21.1 The Contractor agrees that the Commission and any other appropriate agent of the State or Federal Government, or any of their duly authorized representatives, shall have access during reasonable hours to the Contractor's or Subcontractor's facilities and the right to examine Contractor's or Subcontractor's contract files, documents and records involving transactions related to this Contract.
- 21.2 The Contractor further agrees to include in any Subcontracts relating to this Contract a provision to the effect that the Subcontractor agrees that the Commission and any other appropriate agent of the State or Federal Government, or any of their duly authorized representatives, shall have access to the Subcontractor's facilities and the

right to examine any books, documents and records of the Subcontractor, involving transactions related to the Subcontract and that such books, documents and records shall not be disposed of except as provided herein.

## **22. EQUIPMENT**

- 22.1 The title to equipment purchased through expenditure of funds from the Commission shall remain the property of the Commission unless the Commission, in its sole discretion, agrees to transfer title to the Contractor. The final disposition of all Commission property shall be determined by the Commission in accordance with applicable statutes and rules relating to State Materials Management.
- 22.2 The Contractor agrees to exercise reasonable control over all equipment purchased with capital outlay expense of Contract funds. All Commission equipment lost, stolen, rendered unusable or no longer required for research project operation must be reported immediately to the Commission for disposition instructions. The Contractor shall conduct a physical inventory of Commission equipment, using forms supplied by the Commission, within sixty (60) days after the end of the Contract.
- 22.3 Requests for purchases of capital equipment which were not part of the original budget must be submitted prior to the third quarter of the Contract for all one year Contract awards. The same restriction applies to the final year of multi-year Contract awards. All new requests for purchases of capital equipment must be requested and justified in writing and require the written approval of the Executive Director.
- 22.4 Expenditures submitted for maintenance and/or repairs of equipment necessary to the research may be reimbursed upon approval by the Commission. Upon prior written approval maintenance agreements may be purchased for new equipment acquired under this contract. Maintenance agreements may only be purchased for the duration of the contract under which the equipment was acquired or is to be used. Requests for approval must be made in the Annual Budget Summary or in a Budget Transfer Request.

## **23. INFRINGEMENT OF PATENTS AND COPYRIGHTS**

- 23.1 Unless the contractor is an agency insured pursuant to A.R.S. § 41-621, *et seq.*, the Contractor, at his/her sole expense, shall defend any claim, action, or suit which may be brought against the Commission for the infringement of United States patents or copyrights arising from the Contractor's use of any equipment, materials, or information prepared or developed in connection with performance of this Contract. In any such claim, action, or suit the Contractor shall satisfy any final judgment for such infringement. The Commission shall give the Contractor written notice of such claim, action, or suit together with full information. The Commission shall cooperate with the Contractor with regard to any claim, action, or suit. The Commission, acting in its sole discretion may participate in the defense of any such claim, action, or suit if principles of governmental or public law are involved,

however, if the Commission participates it shall not assess its costs or expenses to the Contractor under this subsection without the Contractor's written consent.

- 23.2 If, in the Contractor's opinion, the equipment, materials or information mentioned in Section 22 above is likely to or becomes the subject of a claim of infringement of a United States patent or copyright, then without diminishing the Contractor's obligation to satisfy any final award, the Contractor may, with the Chairman's written consent, substitute other equally suitable equipment, materials and information, or at the Contractor's option and expense, obtain the right for the Contractor or the Commission to continue the use of such equipment, material and information.

## **24. ARIZONA LAW**

This Contract is governed by the laws of the State of Arizona including the Arizona Procurement Code (A.R.S. Title 41, Chapter 23) and the Arizona Procurement Code Rules and Regulations (A.C.C.R. Title 2, Chapter 7).